THE REPORT OF THE
MANITOBA PEDIATRIAC
CARDIAC SURGERY INQUEST:

AN INQUIRY INTO TWELVE DEATHS
AT THE WINNIPEG HEALTH
SCIENCES CENTRE IN 1994

ASSOCIATE CHIEF JUDGE MURRAY SINCLAIR

PROVINCIAL COURT OF MANITOBA

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EXECUTIVE SUMMARY

During 1994, 12 children died while undergoing, or shortly after having undergone, cardiac surgery at the Winnipeg Health Sciences Centre.

In February 1995, following an external review of its Pediatric Cardiac Surgery Program, the HSC announced that it was suspending the program, initially for six months. Following this announcement, many parents of the children who had died demanded a public inquiry into the events surrounding the deaths of their children. On March 5, 1995, the Chief Medical Examiner for the Province of Manitoba ordered an Inquest into the deaths of the 12 children.

The Inquest commenced hearings in December 1995. The final hearings were held in the fall of 1998. In total, more than 80 witnesses testified during more than 285 days of hearings over a period of almost three years. Close to 50,000 pages of transcript evidence were produced, and hundreds of documents exceeding 10,000 pages of material were filed as exhibits in these proceedings.

Such lengthy, complex and controversial hearings do not give rise to easily summarized conclusions. The findings and recommendations in the report flow out of the events that are detailed in the following report.

This summary points to four central themes that became apparent during the course of this Inquest and are elaborated upon in the findings and recommendations.

THE CHILDREN AND THEIR PARENTS

The evidence suggests that the Pediatric Cardiac Surgery Program at the Health Sciences Centre did not provide the standard of health care that it was mandated to provide and that parents believed—and had a right to expect—that their children would receive in 1994.

GARY CARIBOU, born August 22, 1993, underwent a heart operation on March 14, 1994, and died on March 15, 1994. He was six months twenty days old. The evidence suggests that this death was possibly preventable.

JESSICA ULIMAUMI, born August 18, 1993, underwent cardiac surgery on March 24, 1994. She died on March 27, 1994. She was seven months nine days old. The evidence suggests that this was a preventable death.

VINAY GOYAL, born March 2, 1990, had two operations in 1994, the first on March 17, and the second on April 18. He died during the second operation. He was four years one month sixteen days old. The evidence suggests that this was a preventable death.

DANIEL MARKUS TERZISKI, born March 18, 1994, underwent cardiac surgery on April 20, 1994. He died the same day. He was 33 days old. The evidence suggests that the chances of preventing this death would have been increased if Daniel had been referred out of province.

ALYSSA STILL, born November 14, 1993, had heart surgery on May 5, 1994. She died May 6, 1994. She was five months twenty-two days old. The evidence suggests that this death might have been preventable.

SHALYNN PILLER, born July 20, 1994, had surgery on August 1, 1994. She died August 3, 1994. She was 14 days old. It is not possible to determine on the basis of the evidence if this was a preventable death.

ARIC BAUMANN, born December 7, 1993, underwent cardiac surgery on June 30, 1994. He died on August 21, 1994, due to a pre-existing, undetected, congenital fatal condition. He was eight months fourteen days old when he died. The evidence suggests that this was not a preventable death.

MARIETESS TENA CAPILI, born December 15, 1991, underwent surgery on September 13, 1994. She died September 14, 1994. Marietess was two years nine months old. The evidence suggests that this was a preventable death.

ERICA NICOLE BICHEL, born September 29, 1994. Erica underwent a heart operation on October 4, 1994. She died while still in the operating room. She was five days old. While the evidence suggests that Erica would have stood a better chance of survival in the hands of a more experienced surgeon and surgical team, the evidence also suggests that it is not likely that this death was preventable.

ASHTON JOHN FEAKES, born April 15, 1993, underwent heart surgery on November 1, 1994. He died November 11, 1994. He was one year three months twenty-seven days of age. The evidence suggests that this was a preventable death if Ashton had been referred to a larger medical centre.

JESSE WILLIAM MAGUIRE, born November 25, 1994, underwent heart surgery on November 27, 1994. He died while still in the operating room. He was two days old. The evidence suggests that this was a preventable death.

ERIN PETKAU, born December 17, 1994, underwent heart surgery on December 20, 1994. She died on December 21, 1994. She was three days old. The evidence suggests that this death was possibly preventable.

Parents took their children to the HSC's pediatric cardiac program at the recommendation of family physicians. They were assured that the team had the skills and experience necessary to treat their children's complex lesions. This was not always the case. The evidence suggests that at least five of the deaths in 1994 were preventable and several more were possibly preventable. Furthermore, the evidence suggests that in most of the cases parents were not provided with sufficient information to allow them to provide fully informed consent to surgery.

These findings give rise to numerous recommendations relating to any future pediatric cardiac surgery program in Winnipeg and policies regarding consent and funding for the families.

THE 1994 RESTART OF THE PROGRAM

In 1994 the pediatric cardiac program at the HSC recommenced the provision of surgical services. The program at the time had a new surgeon and a new director of pediatric cardiology. Furthermore, three cardiologists had left the program and had not been replaced. These facts should have led to a phased and well-supervised approach to case selection, to ensure that the surgical team did not attempt cases that were beyond its capabilities.

The evidence suggests that the restart of the program suffered from flaws in:

- the recruitment process
- preparation prior to the restart of surgery
- lines of authority
- staffing
- case selection.

The lack of supervision and of a phased start-up plan meant that the Pediatric Cardiac Surgery Program was marked by poor case selection throughout 1994. The evidence suggests that the program continually undertook cases that were beyond the skill and experience of the surgeon and the team. These findings give rise to a series of recommendations for changes in recruiting, staffing and lines of authority.

QUALITY ASSURANCE

The evidence presented to this Inquest suggested that there was a failure of quality assurance and monitoring of the Health Sciences Centre Pediatric Cardiac Surgery Program. This failure involved mechanisms that were internal to the HSC and those that were external to it. The Inquest Report makes two types of recommendations in regard to these issues. It recommends changes to existing internal and external review and monitoring practices and agencies. In addition, the Report recommends that the Health Sciences Centre develop ongoing policies of team building, risk management and quality assurance. This approach is detailed in the body of the Report.

TREATMENT OF NURSES

Throughout 1994, the experiences and observations of the nursing staff involved in this program led them to voice serious and legitimate concerns. The nurses, however, were never treated as full and equal members of the surgical team. This treatment mirrored the way in which nurses believed recent changes in hospital organization had reduced the status of their profession. The Inquest makes recommendations intended to bring nurses into the monitoring process and change the structure of the HSC.

THE FUTURE OF PEDIATRIC CARDIAC SURGERY IN MANITOBA

The available information suggests that the limited number of cases that can be undertaken in a province like Manitoba, with a population of just over one million, represents an increased risk of morbidity and mortality, particularly in the case of high-risk surgery. Even if the catchment area were expanded, the base population would still not be large enough to support a full service program. The Inquest recommends pediatric cardiac surgery be re-initiated in Manitoba only as a part of a regional program in Western Canada.

TABLE OF CONTENTS

Executive Summary v
Table of contents ix
Introduction xxv
Acknowledgements xxvii

SECTION ONE

CHAPTER 1 – INTRODUCTION TO ISSUES

Introduction 3
The calling of the Inquest 5
The mandate of the Inquest 6
Standing 6
Culpability 8
The issue of consent 10
The law of medical consent 10
  A summary of the applicable legal principles dealing with medical consent 16
The onus of proof in inquest proceedings 18
Medical Standards Committees and privilege 18
In camera proceedings 19
Disclosure 21
The taking of evidence 21

CHAPTER 2 – PEDIATRIC CARDIAC ISSUES
HOW THE HEART FUNCTIONS, CONGENITAL HEART DEFECTS AND THEIR TREATMENT

The human heart 23
How a normal heart works 25
Congenital heart disease 27
  Ventricular failure 27
    Left ventricular failure 27
    Right ventricular failure 28
    Biventricular failure 28
  Shunting 28
Pediatric heart defects and their treatment 28
  Patent ductus arteriosus (PDA) 28
  Septal defects 29
  Tetralogy of Fallot 30
  Atrioventricular canal defect 32
  Coarctation of the aorta 33
  Interrupted aortic arch 33
  Pulmonary stenosis and aortic stenosis 35
  Tricuspid atresia 35
  Pulmonary atresia 36
  Total anomalous pulmonary venous connection 37
  Partial anomalous pulmonary venous drainage 38
  Transposition of the great arteries 38
  Double outlet right ventricle 39
  Hypoplastic left heart syndrome 40
    Supportive care 41
    Reconstruction of the heart 41
    Transplantation 43
Summary 43
Risk and pediatric cardiac surgery 44

CHAPTER 3 – THE DIAGNOSIS OF PEDIATRIC HEART DEFECTS AND THEIR SURGICAL TREATMENT

Special issues in pediatric medicine 45
General issues 45
  An issue specific to cardiac cases 46
Pediatric subspecialties 46
  Pediatric cardiology 47
  Pediatric cardiac surgery 48
  Anaesthetists 49
Nursing 49
How a pediatric cardiac surgery case proceeded 51
  Events leading up to the day of surgery 51
    Diagnosis 51
    Variety Children's Heart Centre clinics 51

Surgical consultation 52
Cardiovascular thoracic conferences 52
Consent 53
Scheduling of the operation 53
Admission to hospital 53
Pre-operative conference 54
Pre-operative anaesthetic evaluation 54
Contact with the child and the family 55
Preparation of the patient 55
The day of surgery 55
Preparation of the operating theatre 55
Operating theatre personnel 56
The team 58
Charts 59
The three phases of the operation 60
Post-surgical care 71
The NICU and the PICU 71
Preparing for intensive care 73
Transfer to the Intensive Care Units 75
Responsibility for care 75

CHAPTER 4 – THE HEALTH SCIENCES CENTRE

Establishment of the Health Sciences Centre 77
The 1994 HSC Reorganization 78
Administrative structure 79
The Board of Directors of the Hospital 79
The President 79
The Vice-Presidents 79
Vice-presidents and portfolios before June 1994 80
Vice-presidents and portfolios after June 1994 82
Issues raised by the reorganization 82
Medical departments 83
Surgical sections 83
Pediatric sections 85
Anaesthetic sections 86
Medical staff 87
Medical Staff Council 88
Medical Advisory Committee 88
Remuneration 89
Nursing 89
The Division of Pediatrics and Child Health Nursing – Patient Service Division (Pediatrics and Child Health) 89
The Nursing Council 91
Perfusionists 91
Staff discipline 92
Committees whose activities touched upon the events of 1994 92
The Pediatric Operating Room Committee 92
The Children's Hospital Management Advisory Committee 93

Quality assurance 93
  Quality Assurance Committee 93
  Morbidity and Mortality (M & M) Rounds 93
  Incident reports 94
The College of Physicians and Surgeons of Manitoba 94
The Manitoba Association of Registered Nurses 96
The Office of the Chief Medical Examiner 96
Budgeting 97
The relationship between the HSC and the Faculty of Medicine 98

SECTION TWO

CHAPTER 5 – PEDIATRIC CARDIAC SURGERY IN WINNIPEG 1950–1993

Introduction 101
The start of pediatric cardiac surgery at Children's Hospital—the Ferguson-Cumming Era: 1950s-1981 101
The Collins era: 1982–1993 102
  Collins's background and vision 102
  Relations between HSC and St. Boniface 103
  The Provincial Advisory Committee on Cardiac Services in Manitoba 104
  The establishment of the Variety Children's Heart Centre 105
  Collins and de la Rocha 105
  Recruitment of Dr. Kim Duncan 107
  The matrix concept 107
  The relationship between Collins and Duncan 108
  Collins's role in monitoring performance 109
  The VCHC's caseload 110
  Issues for the Variety Heart Centre 110
    Operating rooms 110
    The VCHC offices 110
    The medical fee schedule 111
    Relations with adult surgery and the hospital administration 111
    Assistance for Duncan 112
    Lack of cases 113
    The number of anaesthetists 113
    Intensive care 113
  Departures 113
  Replacing Duncan 115
    The search committee 115
    Dr. Jonah Odim 116
    Recruitment 118
    Letters of reference 120
    The Boston references 122
    HSC reference questionnaires 123
  Who was in charge? 124

CHAPTER SIX – THE RESTART OF PEDIATRIC CARDIAC SURGERY IN 1994
JANUARY 1, 1994, TO MAY 17, 1994

Problems from the beginning 127
The start-up 128
- January 1994 128
  - Orientation and integration 128
- February 1994 130
  - The restart of the program 130
  - Team building 131
  - The nurses' attempts to initiate an orientation 132
- Case selection 155
- Summary 136

Surgery from February 28 to March 14 137
- February 28—The case of ST 137
- March 7—The case of DR – the first open-heart case 137
  - Odim's lack of familiarity with the OR setup 137
  - Odim's problems with cannulation 138
  - Odim's treatment of nurses 140

The case of Gary Caribou 140
- Issues 140
- Background and diagnosis 141
- The decision to operate 142
- Consent 144
- Pre-operative condition 145
- Conclusion as to Gary's pre-operative status 149
- The operation – March 14 150
- Post-operative course 153
- Autopsy findings 154
- Findings 155
  - Was there an inappropriate delay between the time of Gary's diagnosis and the date of the operation on his heart? 155
  - Was Gary's mother provided with sufficient information to allow her to give informed consent to the procedure? 156
  - Was Gary healthy enough to undergo an operation? 156
  - Did the length of surgery contribute to his death? 157
  - Did a post-operative abdominal drainage procedure contribute to his death? 157
  - What was the cause of death and was it preventable? 158
- Post-mortem issues 159

The case of Vinay Goyal – his first operation 161
- Issues 161
- Background and diagnosis 161
- The decision to operate 164
- Consent 164
- Pre-operative condition 165
- The operation—March 17 165
- Post-operative course 167
  - Overall condition 167
  - Breathing problems 167

Heart problems 168
Concerns of the nurses and the family 168
Decision to reoperate 168
The case of Jessica Ulimaumi 169
Issues 169
Background and diagnosis 169
The decision to operate 172
Pre-operative condition 172
Consent 173
The operation—March 24 173
Post-operative course 176
Autopsy findings 181
Post-mortem events 182
Findings 184
Was there an inappropriate delay between the time of her diagnosis and the date of the operation on her heart? 185
Was Jessica's family provided with sufficient information to allow them to give informed consent to the procedure? 185
Was Jessica healthy enough to undergo an operation? 185
Did the length of surgery contribute to her death? 185
Were the repairs properly carried out? 186
Did irregularities in the process of weaning her from ECMO contribute to her death? 186
What was the cause of death and was it preventable? 187
Should this death have triggered a review of the program? 187
The events of early April 1994 188
April 7 – the case of JM 188
Issues 188
Other PICU issues 190
Surgical monitoring lines 190
Post-operative bleeding and pacemaker malfunction 191
April 13 – the case of CSM 191
Vinay Goyal – the second procedure 193
Consent for the reoperation 193
Delay in the second operation 193
Pre-operative status 194
The operation—April 18 195
Intra-operative incidents 195
Dribbling of adrenalin on the heart 195
Testing the patch 196
The premature removal of a cannula 198
Autopsy 200
Findings 200
Were Vinay's parents provided with sufficient information to allow them to give informed consent to the procedure? 200
Would Vinay have been taken to surgery with a potential infection if his parents had not intervened? 201
Did the surgeon demonstrate the skills and experience necessary to undertake this high-risk surgery? 201
What was the cause of death and was it preventable? 202

Reaction of the PCS team following the deaths of Gary Caribou, Jessica Ulimaumi and Vinay Goyal 202
  The response of the nurses 203
  Perfusionists 206
  Approaches to Wiseman 206
  Anaesthetic meetings 208
  April 18 – Meeting of the Section of Pediatric Anaesthesia 210
The case of Daniel Terziski 210
  Issues 210
  Background and diagnosis 211
  The decision to operate 211
  Consent 212
  Pre-operative status 215
  Preparing the NICU staff 216
  The operation—April 20 217
  Untoward events during surgery 218
    Preparation of the homograft 218
    Removing the cap from the line 218
    Problems with the shunt 220
  The assessment of the consultants 220
  Post-operative Course 221
  Autopsy 223
  Findings 224
    Should Daniel's condition have been diagnosed earlier? 225
    Was Daniel's family provided with sufficient information to allow them to give informed consent to the procedure? 225
    Was Daniel healthy enough to undergo an operation? 225
    Should the HSC team have attempted the operation or should Daniel have been referred out of province? 226
    Should there have been better planning for this procedure? 226
    Did the length of surgery contribute to Daniel's death? 226
    Was there appropriate post-operative care? 226
    What was the cause of death and was it preventable? 227
What happened after the Terziski case 227
  The results up to that time 229
  Ullyot meets with Wiseman 229
  Meetings in late April and early May 230
  Nurses seek reassignment 230
  Odim's view 231
  The existing rounds and conferences 232
The case of Alyssa Still 233
  Issues 233
  Background and diagnosis 233
  The decision to operate 234
  Consent 236
  Pre-operative condition—first admission 236
  Pre-operative condition—second admission 237
  Alyssa's admission to the Children's Hospital 240
  The operation—May 5 240

Post-operative course 243
  Did suctioning contribute to Alyssa's problems? 245
Autopsy findings 246
  The presence of a suture in the coronary sinus 246
  Contraction band necrosis 248
  Edema 248
Cause of death 250
Findings 252
  Was Alyssa's family provided with sufficient information to allow them to give informed consent to the procedure? 252
  Was Alyssa healthy enough to undergo an operation? 253
  Was the PICU adequately equipped for her case? 253
  Were there technical problems with the operation? 253
  What was the cause of death and was it preventable? 253
Borton asks for a transfer 254
May 11–12 – the case of FE 254
The case of RM 256
The anaesthetists withdraw services 257
May 16, 1994 – The meeting of the Section of Pediatric Anaesthesia 257
The May 17 memo from the anaesthetists 258
The distribution of the memo 260
Bishop is notified 260

CHAPTER SEVEN – THE SLOWDOWN
MAY 17 TO SEPTEMBER 1994

The meeting in Bishop's office 261
The decision to conduct a review 263
What to do about the existing cases? 264
Informing HSC senior management 264
Membership on the Wiseman Committee 265
Assessing the problems 266
Were the anaesthetists justified in their action? 267
Options not taken 269
Blanchard speaks with Odim 270
The issue of committee records 270
The first meeting 271
Preparing for the process 273
Nursing concerns 273
  Communication 273
  Morale 274
  Role confusion 274
Anaesthetic concerns 274
  Input into the decision-making process 274
  Communication 274
  Follow-up 275
ICU concerns 275
  Surgical equipment/materials to be available in PICU for emergency and elective procedures in the PICU 275

        - Clarification of areas of responsibility in post-operative management and communication about patient status and proposed changes in therapy, both to the surgeon and from the surgeon 276
    - Surgery and Cardiology concerns 276
- **The anaesthetists agree to return** 277
- **The Wiseman Committee begins its discussions** 277
- **Corporate reorganization takes effect** 278
- **The work of the committee during the month of June** 278
    - The trip to Saskatoon (June 13–14) 279
- **The case of VM** 280
- **The June 29 committee meeting** 281
- **Conflict over out-of-province referrals** 283
- **Swartz's notes** 284
- **Craig and Odim meet** 285
- **The case of Aric Baumann** 285
    - Issues 285
    - Background and diagnosis 286
    - The decision to operate 288
    - Consent 288
    - Admission to the hospital 290
    - The operation-June 30 290
    - Post-operative course 292
    - Autopsy 294
    - Findings 294
        - Could Aric's pulmonary vein stenosis have been identified before surgery? 294
        - Would Aric have benefited from a heart-lung transplant? 295
        - Was Aric a high-risk patient at a time when the program was not undertaking high-risk cases? 295
        - Were Aric's parents provided with sufficient information to allow them to give informed consent to the procedure? 295
        - What was the cause of death and was it preventable? 296
- **Kim Duncan's visit** 296
- **The case of SK** 296
- **The case of KZ** 297
- **The July 13 Wiseman Committee meeting** 298
- **The July 27 committee meeting** 298
- **Nurses and the Wiseman Committee** 300
- **The issues raised by Odim** 301
    - Communications 302
    - Team meetings 302
    - Post-operative care and anaesthesia 303
    - Odim responds to concerns about cannulation 303
- **The case of Shalynn Piller** 303
    - Issues 303
    - Background and diagnosis 304
    - The decision to operate 306
    - Consent 306
    - Pre-operative status 307
    - The operation-August 1 307
    - Post-operative course 308

Post-mortem findings 311
Findings 311
Were Shalynn's parents provided with sufficient information to allow them to give informed consent to the procedure? 311
Should the program have undertaken this operation at a time when neonates were supposed to be sent out of the province? 311
What was the cause of death and was it preventable? 312
Pressure builds for a return to full service 312
The August 10 committee meeting 313
The tricuspid atresia case 313
Post-operative care 313
Forthcoming cases 314
The draft interim report 314
The interim report is distributed 319
The Wiseman Committee plans to return to full service 320
The anaesthetists agree to return to full service 321
The return to full service 321
Conclusion 323
Communication 324
Decision-making 324

CHAPTER 8 – EVENTS LEADING TO THE SUSPENSION OF THE PROGRAM SEPTEMBER 7, 1994 TO DECEMBER 23, 1994

September 7—the return to full program 325
Craig's meeting with the anaesthetists 326
The case of Marietess Tena Capili 327
Issues 327
Background and diagnosis 328
The decision to operate 330
Consent 331
Pre-operative status 332
The operation-September 13 333
Cannulation issues 334
Problems with distension of the heart 336
Surgical bleeding and coagulopathy 336
The superior vena cava syndrome 336
Post-operative course 338
The family on the day of surgery 339
Operative reports 340
Post-mortem findings 342
Findings 342
Should the operation have been performed in Winnipeg or should Marietess have been referred out of province? 342
Were Marietess's parents provided with sufficient information to allow them to give informed consent to the procedure? 343
What caused the superior vena cava syndrome? 343

Should the surgical team have kept Marietess in the OR until
the cause of the superior vena cava syndrome from which she was suffering was identified? 344
What was the cause of death and was it preventable? 345
The appointment of Dr. Andrew Hamilton 346
Dr. Brian Postl is appointed head of pediatrics 346
September 20—the case of ML 347
Wiseman's memorandum to the department heads 348
Odim's letter of September 26 348
September 27—the case of JB 352
The September 28 meeting of the Wiseman Committee 352
September 30—the meeting of department heads 353
The end of September: the nurses are distressed 354
Whistle-blowing 356
The case of Erica Bichel 357
Issues 357
Background and diagnosis 357
The decision to operate 358
Pre-operative status 362
A desperate situation 362
Preparation of the NICU 364
The operation-October 4 364
The issue of cardioplegia 366
The failure to wean from bypass 368
Post-mortem findings 369
Findings 370
Should the Winnipeg team have attempted a Norwood procedure,
given its recent history and its level of experience?
Should Erica have been transferred out of Winnipeg?
Should the operation have taken place before October 4? 371
Were her parents provided with sufficient information
to allow them to give informed consent to the procedure? 372
Was Erica given adequate myocardial protection? 372
What was the cause of death and was it preventable? 373
October 20—the case of ER 373
The Wiseman Committee meeting of October 17 375
The meeting of the anaesthetists on October 19 376
The department heads meeting of October 28 376
The case of Ashton Feakes 377
Issues 377
Background and diagnosis 377
The decision to operate 380
Consent 381
Pre-operative status 383
The operation-November 1 383
Post-operative course 384
Increase in mitral regurgitation 387
November 7—the mitral regurgitation worsens 388
November 8—a small improvement 389

November 9 – a turn for the worse 389
November 10—the opportunity for mitral valve replacement passes 389
November 11 391
Post-mortem findings 391
Findings 393
Were Ashton's parents provided with sufficient information to allow them to give informed consent to the procedure? 394
Should Ashton have been referred out of the province during the summer of 1994? 394
Should consideration have been given to performing a mitral valve replacement before November 10? 395
What was the cause of death and was it preventable? 395
Early Winter 395
November 8—the case of KF 397
November 10—the case of ID 398
The November meeting with Marietess Tena Capili's family 402
The case of Jesse Maguire 403
Issues 403
Background and diagnosis 403
The decision to operate 404
Consent 406
Notifying the OR nurses 407
Hamilton not called in 408
Pre-operative status 408
The operation-November 27 408
Repairing the VSD while on TCA 410
The dislodging of the cannula 412
Post-mortem findings 417
Findings 418
Should the operation have been performed in Winnipeg or should Jesse have been referred out of province? 418
Were Jesse's parents provided with sufficient information to allow them to give informed consent to the procedure? 420
Should Dr. Andrew Hamilton have assisted in this operation? 420
Was a cannula inadvertently dislodged at 1630 hours? 420
Were all the repairs intact? 420
What was the cause of the poor perfusion following the initial repair? 421
Were Jesse's parents fully informed about the circumstances surrounding his death? 421
What was the cause of death and was it preventable? 422
Meeting of the department heads – November 28 423
The impact of the Maguire case 423
The case of JR – December 2 426
Blanchard's meeting with Unruh and Odim—December 5 428
The case of KQ—December 7 429
The Wiseman Committee meeting of December 7 429
Ullyot meets with Postl—December 9 430
The case of Erin Petkau 431
Issues 431
Background and diagnosis 431
The decision to operate and consent 432

- Pre-operative status ... 434
- The operation-December 20 ... 434
- Autopsy findings ... 440
- Findings ... 441
  - Were Erin's parents provided with sufficient information to allow them to give informed consent to the procedure? ... 442
  - Should the ventilation intra-operatively have been different? ... 442
  - Was the Blalock-Taussig shunt too small? ... 443
  - What led to the shunt failures? ... 443
  - Should Dr. Andrew Hamilton have assisted in this operation? ... 444
  - What was the cause of death and was it preventable? ... 444

Reactions to Erin's death ... 445
- Postl calls a meeting ... 446

CHAPTER 9 — 1995 — THE AFTERMATH OF THE SHUTDOWN JANUARY TO MARCH 1995

From Lindsay to Williams and Roy ... 449

The Williams and Roy Report ... 453

Responding to the report ... 454

The role of the President and vice-presidents ... 454

The parents ... 456

The Quality Assurance Committee ... 458

Delays in the autopsy reports ... 458

The College of Physicians and Surgeons ... 459

The Office of the Chief Medical Examiner ... 461

SECTION THREE

CHAPTER 10 — FINDINGS AND RECOMMENDATIONS

Introduction ... 465

The loss and recruitment of program staff before 1994 ... 467
- Loss and recruitment of program staff ... 467
- The compensation paid to pediatric cardiac surgeons ... 470

Problems within the Pediatric Cardiac Surgery Program ... 470
- Unclear lines of authority ... 470
  - The responsibility of department heads ... 470
  - The responsibility of Dr. Jonah Odim and Dr. Niels Giddins for the events of 1994 ... 472
- Misusing the concept of a 'learning curve' ... 472
- Administrative issues ... 473
- Inappropriate staffing levels ... 475

Treatment of nurses ... 477

Treatment of the families ... 479
- The issue of informed consent ... 479
  - The experience of the surgeon and the team ... 479
  - Information about surgical risk ... 480
  - Information about the May 17 withdrawal of services by the anaesthetists ... 480

Information about the Williams and Roy Report and the February 1995 suspension of the program 480
Funding for the families 482
Compensation 483
Monitoring of issues and problems within and outside the HSC 483
Monitoring within the HSC 483
Monitoring outside the HSC 485
Human and medical error 487
Error, accident and humanity 487
Dealing with human error 488
Blaming 488
Learning from human error 488
The investigation of human error 489
Hierarchy of the effects of error 489
The importance of early reaction to error 490
Human factors analysis 491
A new approach to the handling of medical error at the HSC 492
Quality assurance 493
Risk management 494
The integration of quality assurance and risk management 494
Critical incident review policy 495
Team performance 496
The future of pediatric cardiac surgery in Manitoba 498
Combining the ICUs 500
Referral to the College of Physicians and Surgeons of Manitoba 500
Conclusion 501

APPENDIX 1

Glossary of terms used in this report 503

APPENDIX 2

Parties to the proceedings and counsel 511

APPENDIX 3

List of witnesses and dates of testimony 513

DIAGRAMS

Diagram 2.1 Normal Heart (with blood flow) 24
Diagram 2.2 Heart contracting - atrial contractions 26
Diagram 2.3 Heart contracting - ventricular contractions 26
Diagram 2.4 Patent ductus arteriosus 29
Diagram 2.5 Atrial septal defect (ASD) 30
Diagram 2.6 Ventricular septal defect (VSD) 30
Diagram 2.7 Tetralogy of Fallot 31
Diagram 2.8 Atrioventricular (AV) canal defect 32
Diagram 2.9 Coarctation of the aorta 33
Diagram 2.10 Interrupted aortic arch 34
Diagram 2.11 Pulmonary stenosis (valvular) 34
Diagram 2.12 Aortic stenosis (valvular) 34
Diagram 2.13 Tricuspid atresia 36
Diagram 2.14 Pulmonary atresia 36
Diagram 2.15 Total anomalous pulmonary venous connection 37
Diagram 2.16 Partial anomalous pulmonary venous drainage 38
Diagram 2.17 Transposition of the great arteries 38
Diagram 2.18 Double outlet right ventricle 39
Diagram 2.19 Hypoplastic left heart syndrome 40
Diagram 2.20 Functional hypoplastic left heart syndrome 40
Diagram 2.21 Stage 1 of hypoplastic left heart syndrome reconstruction 41
Diagram 2.22 Stage 2 of hypoplastic left heart syndrome reconstruction 42
Diagram 2.23 Stage 3 of hypoplastic left heart syndrome reconstruction 42

Diagram 3.1 Operating room suite 56
Diagram 3.2 Operating room number 2 57
Diagram 3.3 Venous and aortic cannula 66
Diagram 3.4 Aortic cannulation 66
Diagram 3.5 Neonatal intensive care unit 72
Diagram 3.6 Pediatric intensive care unit 74

Diagram 6.1 Gary Caribou – pre-operative heart 143
Diagram 6.2 Gary Caribou – post-operative heart 151
Diagram 6.3 Vinay Goyal – pre-operative heart 163
Diagram 6.4 Jessica Ulimaumi – pre-operative heart 171
Diagram 6.5 Depiction of the connection of the ECMO lines to Jessica Ulimaumi 178
Diagram 6.6 Jessica Ulimaumi – post-operative heart 183
Diagram 6.7 Vinay Goyal – post-operative heart 197
Diagram 6.8 Daniel Terziski – pre-operative heart 213
Diagram 6.9 Daniel Terziski – post-operative heart 219
Diagram 6.10 Alyssa Still – pre-operative heart 235
Diagram 6.11 Alyssa Still – post-operative heart 247

Diagram 7.1 Aric Baumann – pre-operative heart 287
Diagram 7.2 Aric Baumann – post-operative heart 291

Diagram 7.3 Shalynn Piller – pre-operative heart 305
Diagram 7.4 Shalynn Piller – post-operative heart 309

Diagram 8.1 Marietess Tena Capili – pre-operative heart 329
Diagram 8.2 Marietess Tena Capili – post-operative heart 335
Diagram 8.3 Erica Bichel – pre-operative heart 359
Diagram 8.4 Erica Bichel – post-operative heart 365
Diagram 8.5 Ashton Feakes – pre-operative heart 379
Diagram 8.6 Ashton Feakes – post-operative heart 385
Diagram 8.7 Jesse Maguire – pre-operative heart 405
Diagram 8.8 Jesse Maguire – post-operative heart 409
Diagram 8.9 Erin Petkau – pre-operative heart 433
Diagram 8.10 Erin Petkau – post-operative heart 435

TABLES

Table 6.1 Persons involved in the operation on Gary Caribou, March 14, 1994 150
Table 6.2 Length of phases of the operation on Gary Caribou, March 14, 1994 150
Table 6.3 Persons involved in the operation on Vinay Goyal, March 17, 1994 166
Table 6.4 Length of phases of the operation on Vinay Goyal, March 17, 1994 166
Table 6.5 Persons involved in the operation on Jessica Ulimaumi, March 24, 1994 173
Table 6.6 Length of phases of the operation on Jessica Ulimaumi, March 24, 1994 173
Table 6.7 Persons involved in the operation on Vinay Goyal, April 18, 1994 195
Table 6.8 Length of phases of the operation on Vinay Goyal, April 18, 1994 195
Table 6.9 Persons involved in the operation on Daniel Terziski, April 20, 1994 217
Table 6.10 Length of phases of the operation on Daniel Terziski, April 20, 1994 218
Table 6.11 Persons involved in the operation on Alyssa Still, May 5, 1994 241
Table 6.12 Length of phases of the operation on Alyssa Still, May 5, 1994 241

Table 7.1 Persons involved in the operation on Aric Baumann, June 30, 1994 290
Table 7.2 Length of phases of the operation on Aric Baumann, June 30, 1994 290
Table 7.3 Persons involved in the operation on Shalynn Piller, August 1, 1994 308
Table 7.4 Length of phases of the operation on Shalynn Piller, August 1, 1994 308

Table 8.1 Persons involved in the operation on Marietess Tena Capili, September 13, 1994 333
Table 8.2 Length of phases of the operation on Marietess Tena Capili, September 13, 1994 333
Table 8.3 Persons involved in the operation on Erica Bichel, October 4, 1994 366
Table 8.4 Length of phases of the operation on Erica Bichel, October 4, 1994 366
Table 8.5 Persons involved in the operation on Ashton Feakes, November 1, 1994 384
Table 8.6 Length of phases of the operation on Ashton Feakes, November 1, 1994 384
Table 8.7 Persons involved in the operation on Jesse Maguire, November 27, 1994 408
Table 8.8 Length of phases of the operation on Jesse Maguire, November 27, 1994 410
Table 8.9 Persons involved in the operation on Erin Petkau, December 20, 1994 436
Table 8.10 Length of phases of the operation on Erin Petkau, December 20, 1994 436

INTRODUCTION

This document is the final report of the Pediatric Cardiac Surgery Inquest. Readers are advised that there are three sections to this report.

Section One of this report outlines the legal, medical, and organizational issues that the Inquest addressed and contains four chapters. Chapter One deals with legal issues. Chapter Two outlines the pediatric cardiac anomalies that are discussed in this report. Chapter Three provides an introduction to the various medical professions involved in treating these anomalies and the steps through which a pediatric cardiac patient would have progressed in Manitoba in 1994. Chapter Four outlines the structure and staff of the Winnipeg Health Sciences Centre in 1994.

Section Two is a narrative account of events in the Pediatric Cardiac Surgery Program. Chapter Five outlines the program's history up until January 1994. Chapters Six, Seven and Eight recount the program's history in 1994, providing detailed accounts of the events surrounding the deaths of the twelve children whose cases are under examination in this report. Specific findings are made at the end of the discussion of each case. Chapter Nine recounts the events of 1995 up until the calling of this Inquest.

Section Three contains only one chapter, Chapter Ten. This chapter contains further findings, which provide an understanding of why these deaths occurred, as well as recommendations for the prevention of future deaths.

Throughout the report there are numerous diagrams illustrating specific heart anomalies, procedures, and areas in the Winnipeg Children's Hospital. In addition, there are pre-operative and post-operative representations of the hearts of the twelve children who died in 1994. Readers should be aware that these illustrations are generic diagrams, meant to assist in understanding the text. These diagrams are not intended to be anatomically accurate nor are they intended to represent detailed drawings of each specific child's heart. Doctors Glenn Taylor and Jan Davies provided extensive advice in the preparation of these drawings. They are, however, the product of the Inquest.

A NOTE ON SOURCES

This report is based on the evidence that was presented to the Inquest. The evidence and transcripts will be available through the Provincial Archives of Manitoba. However, *in camera* testimony will not be made available to the public. The report does not identify certain children who successfully underwent cardiac operations in the Children's Hospital in 1994. Although the transcripts and evidence do identify the names of those children, readers are reminded that information about their cases was deemed to have been given *in camera* and therefore restrictions on public dissemination of their identities and cases apply.

Quotations from the oral testimony presented to this Inquest are cited by referring to the page or pages of transcript of the evidence. The evidence of the first witness to appear before this Inquest, Dr. Cameron Ward, makes use of a different numbering system than the rest of the transcripts. As a result quotations from his transcript are cited as being from the Evidence of Dr. Cameron Ward. Documentary evidence is identified by the exhibit and document numbers that were assigned to them by the court.

ACKNOWLEDGEMENTS

Putting together a report of this magnitude and managing the process that led up to it, is an impossible task for one person. Many people contributed to this report and to that process.

Christina Kopynsky, Q.C., and Don Slough fulfilled their role as Crown counsel and the Inquest proceedings admirably. They reviewed all documents, interviewed and organized the calling of all the witnesses, prepared 'will-says' for counsel for the various parties summarizing anticipated witness testimony, and prepared excerpts from the exhibits and transcripts for hearings. Additionally, they each participated in the management of Inquest staff. They fulfilled their public responsibilities in a highly professional manner.

Donna Jorgerson and Debby Tack undertook the duties of court clerk for the Inquest hearings. They managed the thousands of pages of exhibits that were filed and operated the courtroom computer and projector. They also contributed to the smooth operations of the proceedings.

Thomas Fone and Paul Cech-Manek, Sheriff Officers, provided courtroom security.

Lanyse Guay was seconded from the Chief Medical Examiner's office for a short while as a Medical Investigator. She was replaced by Betty Owen-Nordrum, RN, who organized the medical charts so that they made sense to non-medical people. She also prepared case summaries from the charts of each of the twelve children, participated in interviewing witnesses, assisted counsel for all the parties with locating medical and other information when asked, and found material needed for the final report. She coordinated the preparation of the diagrams and medical drawings used in the report, as well as helped in proof-reading it. Her contribution was immeasurable.

Kathy Bhola kept the office organized, running the Inquest's administrative operations, maintaining records, and performing numerous other tasks. She would be an asset in any organization. Tera Cooper, Krista Sommer, and Agatha Kostefko were the Inquest's administrative assistants.

Dr. Jan Davies taught us all about human error and human factors analysis. Much of the information and material in this report on those subjects is a result of her work. She also assisted in proof-reading the final draft of the report.

Dr. Glenn Taylor provided invaluable assistance in the diagrams and drawings used in the report, especially with those drawings intended to represent the hearts and anomalies of each of the twelve children.

Cindy Chuckree created the illustrations that appear in this report.

Law students Kelly Moar and Rachel Charette read and summarized thousands of pages of documents and transcripts, and researched numerous legal issues. Jock Bates did the copy-editing, and the staff of Manitoba Culture, Heritage and Tourism – Information Resources Division supervised the printing and web-site development.

The firm of Finlayson Reid Reporting Services provided transcripts for the Inquest on a daily basis.

The professional expertise and patience of Steven Rosenberg, Debbie Crump and the staff of Doowah Design, who undertook the design and layout of the Report, is also gratefully acknowledged.

Finally, Doug Smith performed two important roles for the Inquest – those of researcher and writer. Armed with a remarkable ability to flesh out a series of ideas, thoughts and concepts into a highly polished written state, he put in countless hours reading transcripts and documents to become familiar with the material and to check sources, facts and quotations. His ability to digest and understand huge amounts of detail and information is impressive, but more importantly, his dedication to completion of a task, even one as enormous as this, was inspiring. I was very fortunate to have been able to convince him to work with me on this.

While all of the people mentioned played a role in the development of this report, its contents including any errors are my responsibility.

ASSOCIATE CHIEF JUDGE MURRAY SINCLAIR

Section 1

Chapter 1

INTRODUCTION TO ISSUES

INTRODUCTION

Pediatric cardiac surgery is one of the most professionally difficult and personally satisfying medical disciplines in which to work. It demands precision and accuracy from the surgeon, as well as a high degree of efficiency and teamwork from the other doctors, nurses and technicians who form its operating-room teams. It is a field of medicine that has as its focus the very symbol of love and life in our society: the human heart. Pediatric cardiac surgery offers the promise of life to those who will otherwise die, and it offers to parents the opportunity to continue to raise and love a child they have been told might otherwise be lost to them.

Children with potentially fatal heart problems represent a particularly powerful symbol of vulnerability. Born with a condition that they had no hand in creating, they rely totally on adults to do what can and needs to be done to give them an opportunity to survive and to live as normal a life as possible. Invariably, the survival of children with heart problems depends on some sort of medical intervention. Recent medical developments, particularly in the field of surgery and pharmacology, have come to offer such children greater and greater hope for a long life well into adulthood.

Surgeons these days are performing medical feats on children's hearts that their professional predecessors would have considered impossible. Today, children's hearts are routinely opened, closed and rearranged in a manner that medical professionals of the past never dreamed of. These children can and often do go on to live in a manner that makes them no different from any other child.

But not all surgical outcomes are so rewarding. There are very few pediatric cardiac surgical cases that come with a one hundred per cent guarantee of success. As with any surgical procedure, almost all cardiac surgery has a small degree of risk associated with it.

Recognizing that risk, ensuring that the patient understands that risk before agreeing to surgery and performing its tasks in a manner that does not exacerbate that risk are primary obligations of the surgical team.

It is in keeping with the latter point that medicine has developed the aphorism "First, do no harm."

During 1994, 12 children died while undergoing, or shortly after having undergone, cardiac surgery at the Children's Hospital of Winnipeg.

GARY CARIBOU, born August 22, 1993, was the son of Charlotte Caribou and Morris Dell of Lynn Lake, Manitoba. He underwent a heart operation on March 14, 1994, and died on March 15, 1994, in the pediatric intensive care unit (PICU), within twenty-four hours of surgery. He was six months twenty days old.

JESSICA ULIMAUMI, born August 18, 1993, was the daughter of Emalee and John Ulimaumi of Arviat in the Northwest Territories. She underwent cardiac surgery on March 24, 1994. She died three days later on March 27, 1994, in the PICU. She was seven months nine days old.

VINAY GOYAL, born March 2, 1990, was the son of Virpan and Sheena Goyal of Winnipeg. Vinay had two operations in 1994, the first on March 17, and the second on April 18. The second operation was necessitated because the first operation was not successful. He died during the second operation. He was four years one month sixteen days old.

DANIEL TERZISKI, born March 18, 1994, the son of Danica and Kiril Terziski of Winnipeg, underwent cardiac surgery on April 20, 1994. He died the same day in the neonatal intensive care unit (NICU) within hours of leaving the operating room. He was 33 days old.

ALYSSA STILL, born November 14, 1993, was the daughter of Donna Still of Thunder Bay, Ontario. Alyssa had heart surgery on May 5, 1994. She died May 6, 1994, in the PICU, within hours of her operation. She was five months twenty-two days old.

SHALYNN PILLER, born July 20, 1994, was the daughter of Sharon and Ken Piller of Carman, Manitoba. Shalynn had a heart operation on August 1, 1994, and died August 3, 1994 within forty-eight hours of surgery. She was 14 days old.

ARIC BAUMANN, born December 7, 1993, was the son of Deanna and Curtis Baumann of Winnipeg. Aric underwent cardiac surgery on June 30, 1994. He died fifty-two days later on August 21, 1994, never having left the PICU. Aric was eight months fourteen days old when he died.

MARIETESS TENA CAPILI was born December 15, 1991, to Sarah Tena and Benedict Capili of Winnipeg. She had undergone two operations early in life to provide her with temporary relief. Both of them had been performed in 1992 by the pediatric cardiac surgeon then on staff at the Children's Hospital, Dr. Kim Duncan. Marietess was scheduled to undergo a more definitive repair in 1994. She had that operation on September 13, 1994. She died September 14, 1994, within a few hours of being moved from the operating room to the PICU. Marietess was two years nine months old.

ERICA BICHEL was born September 29, 1994, to Judy and James Bichel of Winnipeg. Erica underwent a heart operation on October 4, 1994. She died while still in the operating room. She was five days old.

ASHTON FEAKES was born April 15, 1993, to Linde and John Feakes of Winnipeg. His operation took place November 1, 1994. He died November 11, 1994, while still in the PICU. He was one year three months twenty-seven days of age.

JESSE MAGUIRE was born November 25, 1994, to Lauren Maguire and Richard Shumila of Winnipeg. He had to undergo a heart operation on November 27, 1994. He died while still in the operating room. He was two days old.

ERIN PETKAU, born December 17, 1994, was the daughter of Walter and Barbara Petkau of Morden, Manitoba. Her heart operation took place on December 20, 1994. She died in the early morning hours of December 21, 1994 in the NICU shortly after leaving surgery. She was three days old.

The surgeon involved in these cases, Dr. Jonah Odim, had assumed the position of Chief of Service, Pediatric Cardiac Surgery at the Children's Hospital in February 1994. This was his first staff appointment and the operations he performed at the Children's Hospital were the first that he had undertaken without supervision.

Throughout 1994, concerns about the deaths of each of these 12 children and about the condition of children from other operations had been expressed to people in authority at the hospital by members of the nursing and medical staff, particularly the surgical and intensive care nurses and the doctors in the Section of Pediatric Cardiac Anaesthesia.

In May 1994, following the death of the fifth of the 12 children, the members of the Section of Pediatric Cardiac Anaesthesia unanimously agreed to refuse to participate in any further pediatric open-heart cases until a review had been undertaken. A review committee was appointed and the program continued to provide services for low-risk cases during the review period. Cases that could not await the outcome of the review were transferred to pediatric cardiac surgical facilities in other provinces. During this period of reduced services, two more children died following surgery in Winnipeg.

The review committee recommended that the program return to full service in September 1994. From that point until December 21, 1994, five more children died.

After the death of the twelfth child, the Head of the Children's Hospital directed that no further pediatric cardiac patients be referred for surgery to the Pediatric Cardiac Surgical Program until a review could be completed by an outside review team.

The outside review team presented its findings to the hospital in early February 1995. On receipt of the review, the HSC suspended the program for a further six months and issued a press release to that effect. Following this announcement the parents of the children who had died became aware for the first time of problems with the program in 1994 and some of them demanded a public inquiry into the events surrounding the deaths of their children.

THE CALLING OF THE INQUEST

The parents' demand for a public inquiry was communicated to the Minister of Justice. On March 5, 1995, following a meeting with the Minister of Justice and other representatives of the Department of Justice, Dr. Peter Markesteyn, Chief Medical Examiner for the Province of Manitoba, ordered that an inquest be held into the deaths of the 12 children. He directed that one inquest be convened to investigate all the 1994 deaths. The Minister of Justice declined to appoint a public inquiry, indicating that the matter might be reconsidered once the inquest had reported.

Inquest hearings began in the summer of 1995, with various parties applying for standing.

THE MANDATE OF THE INQUEST

Inquests in Manitoba are governed by statute, and to a certain extent by common law. Their legislative mandate is set out in the provisions of *The Fatality Inquiries Act, C.C.S.M. c. F-52* (hereafter referred to as the *Fatality Inquiries Act*).

Inquests in Manitoba are presided over by judges of the Provincial Court of Manitoba (*Fatality Inquiries Act*, s. 26). Their primary role is to determine the identity of the deceased, the facts surrounding the death, how the deceased came to die, and whether the death was preventable. Additionally, an inquest is mandated to inquire into whether any of the policies or programs of an institution or government should be changed in order to prevent a repeat of such a death (*Fatality Inquiries Act*, s 33(1)).

During the course of these proceedings, a number of legal issues presented themselves in addition to the legal issues that normally arise with respect to the admissibility of evidence. These issues include the following:

- Who should have standing
- The question of culpability
- What is informed consent
- The legal privilege of members of Medical Standards Committees
- *In camera* proceedings
- Disclosure of evidence

STANDING

A number of individuals and organizations interested in the outcome of these proceedings applied for standing early on in the process.

At common law, the public has no inherent right to attend inquest hearings (Granger: *Canadian Coroner Law*, 1984, The Carswell Company Limited, at page 243). Additionally, no one else had such a right, even the deceased's family. The *Fatality Inquiries Act* of Manitoba now provides that a person who, in the opinion of the presiding Judge, is "substantially and directly interested" in the inquest, may attend the inquest in person or by counsel and may examine or cross-examine witnesses called at the inquest. (*Fatality Inquiries Act*, s. 28(1)).

A Provincial Judge may limit examination or cross-examination of witnesses by a party granted standing where "the examination or cross-examination. . .is beyond what is necessary for the purpose of the Inquest."

The question of determining when a party is "substantially and directly interested in the Inquest" has been the subject of some consideration in the case law (Granger: *Canadian Coroner Law, supra*, at page 217 and page 307 *et seq*).

Based on the principles set out in those cases, and upon the facts of this case, certain individuals and groups of individuals were granted standing to participate in these proceedings. In October 1995, standing was granted to the following:

1. The families of the 12 children were granted full standing.

Although not all families sought standing, their right to standing was declared and recognized from the outset. Counsel appeared for the Terziski, Still, Baumann, Tena, Capili, Feakes, Maguire and Petkau families. The Caribou, Ulimaumi, Goyal, Piller and Bichel families neither appeared personally nor via counsel to ask questions or make submissions, despite being notified of their right to do so.

Additionally, while the Caribou, Goyal, Piller and Bichel families declined to appear via counsel or to examine witnesses, members of those families did testify. However, John and Emalee Ulimaumi, parents of Jessica, declined to attend in order to testify. Despite the obvious importance of their version of the events concerning their daughter, it was decided not to pursue the matter, especially given the magnitude of their loss, and the fact that much of what occurred concerning Jessica's death could be otherwise determined.

2. The Health Sciences Centre was granted full standing.

3. The Department of Health of the Province of Manitoba was granted full standing.

4. The Manitoba Association of Registered Nurses, representing the nurses involved in the care of the 12 children, was granted full standing.

5. The pediatric cardiac anaesthetists and pediatric intensivists involved in the care of the 12 children were granted full standing, to be represented by one counsel.

6. A group consisting of Dr. Jonah Odim and other surgeons involved in pediatric cardiac surgery at the Health Sciences Centre in 1994 was granted full standing.

7. A group consisting of neonatologists and other physicians involved in the delivery of medical care to patients in the neonatal intensive care unit in 1994 was granted full standing.

8. HSC pathologists were granted limited standing.

Standing was granted to each of the parties on the basis that they had a real and direct interest in the proceedings. Obviously the status of the families in that regard could hardly be questioned. The interest of the HSC in the proceedings was also deemed to be direct and substantial, given the issues of supervision and accountability that were raised by the evidence. Similarly, the Department of Health's role in funding and monitoring the hospital and the program was raised in the course of these proceedings, causing a substantial and direct interest to arise on their part.

The participation of the various medical professionals in the care and treatment of the 12 children who died resulted in sufficient interest on their part to justify standing. Additionally, however, because much of the evidence concerned personality conflicts between members of the health-care team, as well as miscommunication and professional disagreements over treatment, that further justified granting full standing to each of the parties.

At a later point in the hearings, limited standing was granted to a group consisting of the pathologists involved in performing autopsies on the deceased. There was a suggestion that delays in the performance and completion of autopsy reports may have contributed to institutional delay in responding to growing problems within the pediatric cardiac surgery program, and on that basis, counsel for pathologists at the HSC was allowed limited standing to question witnesses who testified about that issue.

CULPABILITY

One of the limitations placed on inquests in Manitoba is that presiding judges are not permitted to make findings of culpability with regard to the deaths they investigate. The limitation is not restricted to presiding judges, however.

Section 7 (6) of the *Fatality Inquiries Act* provides:

> In making an inquiry report under subsection (5), a medical examiner or investigator shall not express an opinion with respect to culpability in such manner that a person is or could be identified as a culpable party.

Section 14 (2) further provides:

> In an investigation report, a medical examiner shall not express an opinion with respect to culpability in such manner that a person is or could be identified as a culpable party.

The limitation on presiding judges is found in section 33(2) of the *Fatality Inquiries Act*, which provides:

> In a report made under subsection (1), a Provincial Judge
>
> (a)...
>
> (b) shall not express an opinion on, or make a determination with respect to, culpability in such manner that a person is or could be reasonably identified as a culpable party in respect of the death that is the subject of the Inquest.

Coroners' inquests once had the right to accuse persons of being responsible for the death of a deceased person, and to issue arrest warrants for those named. Such powers were taken away by statute, but inquests continued to be allowed to name those responsible for the death if they found sufficient evidence to do so. That ability was taken away by legislative amendment in 1990 (*S.M. 1989–90*, c.30).

While "culpable" and "culpability" are not defined in the legislation, culpability is nothing more than legal blaming. To find someone culpable is to determine that an individual has committed an act (either by commission or by omission) that amounts to a legal transgression and that the act is legally blameworthy or sanctionable.

The need to limit the ability of presiding officials at inquests to comment upon the issue of culpability is obvious. There are disciplinary, civil and criminal laws and procedures in place that are intended to address the issue of legal culpability. Those laws contain procedures that respect the rights of individuals (such as complainants, witnesses and defendants), including the right to notice, disclosure, counsel, reply, cross-examination etc.

Provisions in fatality inquiries legislation, on the other hand, allow for evidence to be heard informally, sometimes *in camera*, and for persons to be examined in a manner that is not necessarily consistent with the protective procedures that are normally in place during civil and criminal trials. That is because the purpose of such legislation is not to place legal blame but to determine what happened in order to see if what happened can be prevented from recurring.

A potentially culpable party might not be a party to the inquest proceedings. They may not have standing to cross-examine witnesses who might testify as to something that the person may have done to cause the death of the deceased. A potentially culpable party is compellable as a witness and does not have the right to refuse to answer questions under oath. The *Fatality Inquiries Act* of Manitoba deems them to object to testifying as to any potentially culpable behaviour but the *The Manitoba Evidence Act R S. M. 1987, c.E150* requires that they testify if ordered and protects such testimony from being included in other proceedings. However that protection might be moot if it leads to their being identified as a culpable party. The *Canada Evidence Act R. S. C. 1985, Chap. C-5*, which governs criminal proceedings in this country, contains a similar provision. The *Canadian Charter of Rights and Freedoms* protects compelled testimony from being used against a party as well (*Constitution Act 1982, Part 1*, sec 13).

Because of that, it is obvious that evidence may be obtained during the course of an inquest that might not otherwise be admissible in a civil or criminal legal proceeding, or might not have been tested in accordance with the usual procedures. Because safeguards available to an accused or defendant in criminal, disciplinary or civil proceedings may not be available during inquest proceedings, it is necessary to ensure that proceedings under fatality inquiries legislation not result in unfairness to individuals.

All of this is meant to show that there is good reason for the limitation in the legislation against pronouncing on culpability. For the same reason, however, judges presiding at inquests should be reticent about exonerating individuals. While the legislation does not specifically provide for such a limitation, it makes sense that if an inquest judge ought not to find culpability on the part of an individual, the judge should not declare individuals free from culpability.

As an inquest judge, therefore, I accept that I am not permitted to comment on culpability in the course of making my findings. Accordingly, this report will not comment on the culpability of any individual, corporation, group or collective of individuals.

That does not mean, however, that a presiding judge at an inquest cannot make findings of fact or of law in order to reach appropriate conclusions.

In *Swan v. Harris* (1992), 79 Man. R. (2d) (Q.B.), the report of an inquest by a judge referred to allegations of abusive conduct by the victim's father toward his wife and children. The father alleged that the judge exceeded his powers by referring to this abusive conduct, and that the alleged abuse was not relevant to the inquiry as the deaths were not linked to it. Jewers J. at page 191 held that the inquest judge made no finding of culpability. He also stated at pages 191–192 that it was appropriate and within the inquest judge's jurisdiction to receive evidence concerning the alleged abuse. Because there might have been some connection between this abuse and the deaths, it was essential to inquire into this for a full and proper inquest.

Jewers J. stated that had the judge inquired into a subject that was utterly remote and made that a part of the report, then he might have exceeded his powers.

Therefore while a judge cannot declare that a particular act makes a person legally culpable, he can make a finding that a particular act occurred, without declaring on the question of culpability, so long as the finding is relevant to a matter into which he or she is inquiring.

I am aware that civil proceedings have been undertaken as a result of the deaths of some of the children who are the subject of this inquiry. Those proceedings have been held in abeyance pending the completion of these proceedings. That is not to say that any findings from these proceedings will be binding on any other proceedings. That is in fact, and in law, not the case. However, I am aware that the findings of these proceedings may have an influence on the public's perception as to the issues between the parties to the civil proceedings. I intend, therefore, to be as careful as possible; however, that possibility cannot totally determine the content of this report.

Throughout this report, therefore, I intend to make whatever findings of fact, and of law, are essential for me to perform the mandate assigned to me by legislation, but I do not intend to make any findings of culpability. It is important to bear that limitation in mind throughout this report. The question of culpability is for others to decide if asked.

THE ISSUE OF CONSENT

These proceedings have given rise to a clear question of whether the parents of the deceased children gave proper consent to the operations that their children underwent before their deaths.

I recognize that to make a declaration of consent or lack thereof runs the risk of transgressing the very line about which I have spoken on the issue of culpability. To declare that a particular operation occurred without proper consent gives almost immediate rise to the conclusion that the party, or parties participating in the operation engaged in an illegal act, perhaps amounting to an assault on the patient. That is a reasonable conclusion from a finding of a lack of consent.

However, the question of what patients (or in this case parents of patients) were and ought to have been told and, in the future, ought to be told, is a matter that merits the attention of this report. Readers will note later on in the text that the question of what parents were told or ought to have been told is commented upon, but in so doing I have adopted the approach suggested by the case law.

THE LAW OF MEDICAL CONSENT

The law of medical consent has been undergoing changes in recent years. The abiding principle for consent was always that the consent had to be an informed one. Patients were to be told whatever needed to be known about a particular procedure in order that their consent could be valid.

For the most part, the question of what information was to be given to patients in order that they be in a position to give informed consent was governed by the practice of the medical profession. Medical practitioners were generally held to have fulfilled their legal obligation if they provided information to a patient in accordance with the practice among their colleagues.

However, recent case law in Canada, Australia, and the United States suggests that that principle is changing.

Generally, it is the patient, not the surgeon, who decides whether or not surgery will be performed, where it will be performed and by whom it will be performed (*Allan v. New Mount Sinai Hospital* (1980), 109 D.L.R. (3d) 634 at 642, rev'd on a procedural point 125 D.L.R. (3d) 276 (Ont. C.A.)).

Furthermore, a doctor's duty to inform relates to all material risks, including special and unusual risks of treatment. What is material is determined by what the reasonable patient would want to know, and not by what the reasonable doctor would like to disclose (*Hopp v. Lepp* [1980] S.C.R. 192 (S.C.C.) at 204).

Material risks are those risks that pose a real threat to the patient's life, health or comfort (*White v. Turner* (1981), 120 D.L.R. (3d) 269 at 284 (Ont. H.C.), aff'd (1982), 12 D.L.R. (4th) 319 (Ont. C.A.)).

A failure on the part of the doctor to fully inform the patient will generally be dealt with by negligence law, and not by battery (unless there has been misrepresentation or fraud to secure consent). In other words, a lack of properly informed consent does not give rise to an action for the improper application of force (*Reibl v. Hughes* [1980] 2 S.C.R. 880 (S.C.C.), at 891–892).

The fact that a patient has signed a consent form in which it is acknowledged that the nature of the operation has been explained does not necessarily prove that the duty to inform has been observed. The existence of the consent form does not protect the doctor from liability unless the patient has been informed to the satisfaction of the court (*Bickford v. Stiles* (1981), 128 D.L.R. (3d) 515 at 520 (NBQB)).

In an Ontario case, a surgeon who had failed to disclose to his patient that he had little experience with the technique being used was found to be negligent in the performance of the operation. However, on the question of the consent of the patient to the operation, the trial judge held that the surgeon failed in his duty to his patient by failing to disclose his inexperience and failing to give his patient the opportunity to have the procedure performed by another more experienced surgeon (*Miles v. Judges* (1997) 37 C.C.L.T. (2d) 160 (Ont. Ct. Gen Div.)).

In the case of *Hopp v. Lepp* (*supra*, at 197), the surgeon had told the patient that the facilities for performing the operation were as good in Lethbridge as they were in Calgary where the patient had thought of going. Laskin C.J. approved of the trial judge's finding that the operation was a routine one, and that although there was a possibility of complications as there is in any operation, there was no greater probability of complications of the operation being performed at Lethbridge as opposed to Calgary. In other words, there was no evidence that the assurance given by the surgeon was incorrect or that if the operation had been done in Calgary it might have produced a different result.

Every medical practitioner must bring to his task a reasonable degree of skill and knowledge, and must exercise a reasonable degree of care (*Crits v. Sylvester* [1956] O.R. 132 (Ont. C.A.) at 143–144, aff'd [1956] S.C.R. 991). In the same vein, all those involved in the care of the patient, including the referring physician, nurses, anaesthetists and medical managers all owe such an obligation to the patient.

Whether a risk is material and whether there has been a breach of the duty of disclosure are matters that are not determined solely by the professional standards of the medical profession at the time. Professional standards are a factor to be considered, but the ultimate responsibility in determining if the professional met the appropriate standard lies with the court (*Videto et al. v. Kennedy* (1981), 33 OR (2d) 497 (Ont. C.A.)).

It is generally accepted in England that doctors have a duty to exercise reasonable care with their patients. This duty extends not only to examination, diagnosis and treatment, but also to the provision of appropriate information. In determining whether a medical practitioner has breached his or her duty of care to a patient, the courts of England had generally applied the *Bolam* principle, by which a doctor would not be found to be negligent if he or she acted in accordance with the practice accepted at the time as proper by a responsible body of medical opinion (*Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582). This was so even though other doctors might have followed a different practice. The basis of the principle is that it leaves room for differences of opinion in matters involving medical expertise. A medical practitioner would not be held negligent simply because his or her conclusion or approach differs from that of other practitioners.

Whether the *Bolam* principle applies in providing information and advice relevant to medical treatment was reconsidered by the British House of Lords in 1985 (*Sidaway v. Governors of Bethlem Royal Hospital* [1985] 1 AC 871).

In that case, the plaintiff alleged that the defendant surgeon failed to explain the risks of permanent damage to the spinal column (assessed at between one and two per cent), involved in an operation on the spine to relieve neck, shoulder and arm pain. The majority of the House of Lords held that the question of whether a failure to warn a patient of the risks inherent in proposed treatment constituted a breach of a doctor's duty of care was to be determined by applying the *Bolam* principle. Thus the issue was determined primarily on the basis of expert medical evidence, although a majority of the Law Lords took the view that doctors were under a duty to provide a patient with sufficient information.

In his dissenting opinion in *Sidaway*, Lord Scarman expressly rejected the *Bolam* principle in relation to cases involving advice or information. He concluded that while current medical opinion was a relevant consideration, it was not conclusive and it was for the court to decide whether the doctor had given the patient the relevant information to enable the patient to determine whether or not to accept the treatment proposed.

In 1998 the England and Wales Court of Appeal considered and accepted the *Sidaway* decision (*Pearce v. United Bristol Healthcare NHS Trust* [1998] EWJ No. 617), but added that a doctor must inform the patient of significant risks:

> In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law, as indicated in the cases to which I have just referred, that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt. (*Ibid*, at para. 18)

Further, with regard to whether a risk is material and how this is to be determined, the Court stated:

> I am of opinion that the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it. The kind of case I have in mind would be an operation involving a substantial risk of grave adverse consequences, as, for example, the ten per cent risk of a stroke from the operation which was the subject of the Canadian case of *Reibl v Hughes*. In such a case, in the absence of some cogent clinical reason why the patient should not be informed, a doctor, recognising and respecting his patient's right of decision, could hardly fail to appreciate the necessity for an appropriate warning. (*Ibid*, at para. 19)

This decision and the judgment of Lord Scarman in *Sidaway* are based on principles that were enunciated in a leading U.S. case (*Canterbury v. Spence* [1972] 463 F. 2d 772, U.S. Court of Appeals, District of

Columbia Circuit). The U.S. Court of Appeals for the District of Columbia held that a doctor was under a duty to disclose all 'material' risks. A risk was to be considered material if a reasonable person, in what the doctor knew, or ought to know, was the patient's position, would be likely to attach significance to the information in determining whether to forgo or proceed with the proposed treatment.

As well, the U.S. case of *Johnson v. Kokemoor* held that a jury properly heard evidence on the extent of a surgeon's experience in performing a complicated procedure, as well as evidence that compared morbidity and mortality rates between experienced and inexperienced surgeons, and evidence that the plaintiff could have obtained care nearby from more experienced surgeons. The jury concluded that the surgeon had not adequately informed the patient of the risks attending her surgery, including apparently, the risk associated with the level of the surgeon's experience. In this case, the patient posed very specific questions to the surgeon before surgery, questions that the surgeon did not answer fully or accurately (*Johnson v. Kokemoor* Westlaw No. 93–3099, Supreme Court of Wisconsin (20 March 1996)).

The U.S. case of *Canterbury v. Spence* was cited with approval by the Supreme Court of Canada in *Reibl v. Hughes*, in which it was held that the medical practitioner's 'duty to warn' arises from the patient's right to know of material risks, a right that in turn arises from the patient's right to decide for himself or herself whether or not to submit to the proposed medical treatment. The court accepted that expert medical evidence is relevant to a finding as to the risks that reside with recommended surgery or other treatment, and may have a bearing on the question of the materiality of the risk. But it concluded that the question of what risks are to be disclosed is not a question to be concluded on the basis of expert medical evidence alone. Account will be taken of a patient's particular position as well.

In Australia it is generally accepted that the standard of care of doctors is not determined solely by reference to a responsible body of opinion in the relevant trade or profession. In both *Rogers v. Whitaker* (*Rogers v. Whitaker* (1992) 175 CLR 479) and *Chappel v. Hart* (*Chappel v. Hart* (1998) HCA 55), the *Bolam* principle was rejected, and it was accepted that, while evidence of medical practice was a useful guide, in the end it was for the courts to decide the appropriate standard of care in the circumstances.

In *Chappel v. Hart*, Chappel, an ear, nose and throat specialist, performed surgery on a patient, Hart, for the removal of a pharyngeal pouch in her esophagus. Hart would have required the operation eventually but it was still considered elective because she did not need it right away. Hart had expressed concern on what effect the operation might have on her voice. Chappel failed to warn her of a small risk of vocal damage if the esophagus were perforated and an infection set in. During surgery, Hart's esophagus was perforated and infection did set in, which led to a paralysis of the right vocal cord. The failure of Chappel to warn Hart of the risk of damage to her voice was held to have set off a foreseeable chain of events permanently affecting Hart's voice.

While Hart admitted that she still would have undergone the operation even if she had been warned of the risk, she testified that she would have deferred the operation, taken further advice and probably would have sought out the most qualified surgeon available. That surgeon was apparently not Chappel.

There was a difference of opinion between the majority and dissenting judges as to whether surgery by a more experienced surgeon would have carried a lower risk to the patient's voice. The majority of the judges concluded that the risk would have been lower had a more experienced surgeon performed the operation.

More importantly, three of the five judges held that Chappel's failure to advise Hart of the risk led to her undergoing the procedure when and where she did, and vitiated her consent.

The Court therefore clearly held that a medical practitioner is under a duty to inform a patient of any foreseeable risk. It also went further, however, and held that where such a duty arises, it is necessary for the plaintiff to establish what she would have done if the information in question had been provided to her (*Ibid*, at para. 9).

The court in *Chappel* adopted a primarily subjective theory of causation in determining whether the failure to warn would have avoided the injury suffered.

Gaudron J. seemed most influenced by the evidence of a medical professor that suggested that the risk would have been less if Hart had had a more experienced surgeon. He stated:

> It is not in doubt that a risk of perforation and infection was and is inherent in surgery of the kind performed on Mrs. Hart. In that sense, the risk of injury was the same, no matter when or by whom the surgery was performed. However, that is not to say that the likelihood of that risk eventuating was the same.
>
> Professor Benjamin gave evidence from which it might be inferred that the risk of perforation, without which the injury sustained by Mrs Hart could not have occurred, diminished with the skill and experience of the surgeon concerned. (*Ibid* at para 17)

Similarly, Gummow J. found that Hart would not have undergone the procedure by Chappel, but would have wanted "the most experienced person with a record and reputation in the field, such as Professor Benjamin" (*Ibid*, at para. 78). Kirby J. held that "intuition and common sense suggest that the higher the skill of the surgeon, the less is the risk of any perforation of the oesophagus into the mediastinum" (*Ibid*, at para. 97).

Kirby J. also placed considerable significance on the fact that Hart had inquired into a possible risk to her voice. He said, "(t)his was not an ordinary patient. It was an inquisitive, persistent and anxious one who was found to have asked a particular question to which she received no proper answer" (*Ibid*, at para. 99).

In another very recent Australian case, the Court felt that the trial judge erred in failing to take into account the circumstances of the patient in deciding whether she would have undergone the procedure had she been properly informed. (*Percival v Rosenberg* [1999] WASCA 31 (25 May 1999)). It stated:

> Applying the law as discussed in *Chappel* and *Rogers v Whitaker*, the learned trial Judge erred in finding that the respondent was not required to warn the appellant of the risks of TM joint problems and symptoms arising after the procedures which the appellant underwent.
>
> The learned trial Judge rejected the proposition that the appellant would have not had the surgery had she been warned of the possible risks. However, in my view the submission of the appellant's counsel that in coming to an adverse view of the appellant's credibility the learned trial Judge did not take into account the important matter of the severe effects which the complications have had upon the appellant, both physically and mentally, is correct. His Honour did not discuss the ramifications of those matters. (*Ibid*, at paras. 99–100)

Thus the Court agreed that a more subjective approach should be taken when assessing whether a patient would have agreed to the operation.

Rogers v. Whitaker was another case that concerned the obligation of a doctor to advise on material risks. The issue was whether a surgeon should have warned the patient, in advance of an eye operation, of a particular complication shown to occur in one out of 14,000 such operations. Despite the patient expressing her concerns about the operation, the doctor had given her no warning of the risk and the operation proceeded. The patient did develop the complication following surgery, and it led to blindness. The doctor led evidence from a body of medical practitioners that they would not have given such a warning. Then, invoking the protection of *Bolam*, the doctor contended that he was therefore not negligent.

The High Court disagreed and held that he was negligent because he knew that if he had warned the patient about this risk, she would have regarded it as significant. The Court formulated the duty as follows:

> The law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. (*Ibid*, at p. 490)

The *Chappel* decision supported the view that this test was the correct one to apply for determining issues of informed consent. This test is very similar to the test in Canada and seems to be the direction in which the English courts are also heading.

Most of the case law concerning medical consent arises in the field of tort law—that is, the law concerning claims for damages as a result of an improper act or omission. The cases centre on two questions: firstly, whether any consent to treatment was properly obtained; and secondly, if not, whether the lack of consent (or, perhaps more properly, the lack of information that voids consent) directly led to the damage or injury claimed.

The latter issue is not one about which I need be concerned, because of its fundamental attachment to the question of culpability.

Medical case law has made allowances for the fact that where a doctor's decision to treat a patient in a certain manner was reasonable, taking into account the risks involved and based on accepted medical practice, it was logical to conclude that a reasonable person, having been properly informed of the risks, would not have declined the treatment. In other words, a court would not inquire into the question of whether the information not disclosed to the patient would have resulted in the patient doing something different from what was done. The court went only so far as to determine, using the standards of the profession, whether a person acting in a reasonable manner would have declined the operation.

That principle has changed somewhat recently, however. Currently, the approach in failure to inform cases in Canada has moved to using a modified objective test that allows the court to consider the patient's personal circumstances (*Reibl v. Hughes, infra*).

The test now is to determine the matter from the perspective of whether a reasonable person *in the circumstances of the plaintiff* would have consented to the proposed treatment if all the risks had been disclosed.

In 1997, the Supreme Court had occasion to consider the issue once again. A pregnant woman suffered from chicken pox early in her pregnancy. The case centered on the duty of her doctor to disclose to her that the chicken pox entailed risks of serious birth defects for her unborn child. He made no such disclosure to her. The mother sued the doctor for damages after her child was born with serious disabilities as a result of the chicken pox. The mother testified that she would have terminated the pregnancy had she been advised of the risks. The trial judge found that a reasonable woman in the plaintiff's position would not have done that, but would have continued with the pregnancy despite the risks. In other words, her evidence as to what she would have done was not determinative of the matter. A majority of judges in the Supreme Court of Canada agreed with the trial judge and with the test used for causation (*Arndt v. Smith* [1997] 2 SCR 539).

McLachlin J. (as she then was) delivered a separate decision in which she also agreed with the ultimate decision of the trial judge, but enunciated the test for causation to be one that asked what the particular plaintiff would have done in all the circumstances. She also accepted the trial judge's view that the reasonableness of the patient's choice is an important factor bearing on that decision. Both Sopinka J. and Iacobucci J. dissented. They agreed with the test of causation proposed by McLachlin J., but took the view that the trial judge had not applied that test properly by discounting the plaintiff's testimony.

A SUMMARY OF THE APPLICABLE LEGAL PRINCIPLES DEALING WITH MEDICAL CONSENT

From all of this it is possible to discern the following principles:

- It is the patient who decides whether, when, where and by whom surgery is to be performed.
- For a consent to medical treatment to be valid, it must be informed consent.
- What a patient is told is not to be determined solely by what the practice of the profession is, although knowing that practice can assist the court.
- A doctor must inform a patient of all material risks. What is material is determined by asking the question "what would a reasonable patient want to know?"
- Material risks are also those risks that pose a real threat to the patient's life, health, or comfort.
- A failure by a doctor to fully inform a patient is a matter for the law of negligence.
- The fact that a patient has signed a consent form does not determine the issue. It is for the court to determine if the facts show a fully informed consent.
- A surgeon's inexperience can be a factor affecting risk that a doctor must disclose to a patient.
- In Canada, in determining if the patient's consent to a procedure has been fully informed, the court must consider the question of whether all material facts have been disclosed, and if not, whether a reasonable person in the same position as the patient would have gone ahead with the procedure in any event.

In an article by the Hon. Paul de Jersey prepared for the Medico Legal Society of Australia, the question of medical consent was discussed (March 22, 1999. Found at http://courts.qld.gov.au/sc&dc/speeches/medico.htm). De Jersey points out that there is a change occurring through society in how people view their health, and in what they feel they are entitled to know. There is a movement away from the paternalistic 'doctor knows best' standard to one that involves the patient more, especially when it comes to surgical procedures. De Jersey points out that doctors have not always provided their patients with the information that patients felt they needed or were entitled to, for a variety of reasons. Perhaps, he suggests, that failure stemmed from a desire to protect the patient from anxiety or because it was too time-consuming and difficult. If so, that approach was going to have to change. The case law discussed above seems to support the conclusion that that approach is being reflected in the recent cases.

Technical skills are no longer enough for a doctor to fulfil his or her duties. Doctors must now have good communication skills. The court's finding for the plaintiff in *Chappel* reinforced the view that informed consent requires doctors at the very least, to listen to and respond to the questions and concerns of their patients.

The other cases also suggest that there may also be arising an obligation on the part of doctors to be more proactive in informing patients about matters of risk. Doctors can no longer defend themselves on the basis of what the 'usual practice' of the profession has been.

The decision of the Ontario court (General Division) in *Miles v. Judges* seems to best reflect that change. In that case it will be recalled, the trial judge held it was a doctor's duty to disclose his inexperience with respect to a particular surgical procedure that his patient required. This was so, even though it had generally been accepted that medical practitioners did not normally discuss their surgical experience with patients unless specifically asked.

The need for greater openness within the health system has been demonstrated by a recent medical scandal in England (Commission of Inquiry into the Bristol Royal Infirmary). It resulted in a General Medical Council Inquiry into fifty-three pediatric cardiac operations at the Bristol Royal Infirmary in which twenty-nine children died and four were left with brain damage following surgery.

Formal action by the General Medical Council resulted only after a consultant anaesthetist went over the head of the chief executive officer of the hospital and 'blew the whistle'. The factors that discouraged openness and frankness about a doctor's personal and professional performance were identified as key in explaining how the scandal occurred. It became evident, during the course of the Bristol Inquiry, that the parents of the children who had died had not been told of the significant medical dispute going on in that hospital over whether the hospital should continue to offer certain surgical procedures despite poor results. The General Medical Council suspended two of the doctors involved from practising medicine as a result of their conduct. On June 18, 1998, a Commission of Inquiry was appointed to look into the matter.

In this report, one of the major issues that will be explored is the question of whether the families of the deceased children were fully informed about events within the Pediatric Cardiac Surgery Program at the HSC in 1994. The Report will examine whether that information was something that the parents ought to have known before giving their consent to the surgical procedures involving their children. The Report will also explore the question of what the parents were told about the risks associated with the surgical procedure that their children were about to undergo, as well as the nature of what information surrounding risk they were told and ought to have been told.

In order to make any recommendations concerning what the hospital or government might have to do in the area of informing parents and patients of their rights, or ensuring that those rights are properly respected, conclusions will have to be reached as to what parents were told and whether their consents were or may not have been validly obtained.

In doing so, I recognize that I may be treading close to the line of pronouncing on the culpability of individuals or institutions. I feel, however, that in order to prevent the events of 1994 from being repeated, recommendations should be made about the nature and type of information that patients and their families are entitled to and ought to be provided. Therefore, when discussing this and other areas of similar importance, the language used will need to be carefully considered.

THE ONUS OF PROOF IN INQUEST PROCEEDINGS

The onus of proof in inquest and inquiry proceedings has been a matter of some discussion in the case law. Generally in order to make a finding of fact, a presiding judge, in any proceeding other than a criminal proceeding, needs to be satisfied in accordance with the civil standard of a 'balance of probabilities'.

Furthermore, cases involving inquiries and inquests have given direction on this point to presiding officials. Generally the guidance has been to indicate that protective phraseology should be adopted. Wording such as 'the evidence suggests' is recommended in order to avoid making a finding that leads directly to a conclusion of culpability. I have therefore attempted to do so wherever such phraseology is warranted.

MEDICAL STANDARDS COMMITTEES AND PRIVILEGE

During the course of these proceedings, it became apparent that some of the issues under review had been considered by medical standards committees established by the HSC, as well as by the Manitoba College of Physicians and Surgeons.

Medical standards committees enjoy some immunity from having to reveal their proceedings pursuant to section 9 of the *Manitoba Evidence Act*. That provision states:

> **Evidence as to proceedings of hospital committee, etc., not compellable**
>
> 9(1) A witness in any legal proceeding, whether a party thereto or not, is excused from answering any question as to any proceedings before, or producing any report, statement, memorandum, recommendation, document, or information of, or made by, a committee to which this subsection applies and that is used in the course of, or arising out of, any study, research, or program carried on by a hospital or any such committee for the purpose of medical education or improvement in medical or hospital care or practice.
>
> **Application of subsec. (1)**
>
> 9(2) Subsection (1) applies to all of the committees hereinafter mentioned; namely:
>
> (a) a standards committee appointed under section 26 of The Hospitals Act;
>
> (b) a research committee of a hospital;
>
> (c) a medical staff committee established for the purpose of studying or evaluating medical practice in a hospital; and
>
> (d) a medical research committee recognized by the Minister of Health and approved for the purpose of this section by a regulation made by him.
>
> **Application of *The Regulations Act***
>
> 9(3) *The Regulations Act* applies to a regulation made under clause (2)(d).
>
> **Exception**
>
> 9(4) Subsection (1) does not apply to original medical and hospital records pertaining to a patient.

> **Members of committee, etc., not excused generally**
>
> 9(5) Notwithstanding that a witness in any legal proceeding is or has been a member of, or has participated in the activities of, or has made a report, statement, memorandum, or recommendation to, or has provided information to, a committee to which subsection (1) applies, he is not, subject to subsection (1), excused from answering any question or producing any document that he is otherwise bound to answer or produce.
>
> **Definitions**
>
> 9(6) In this section
>
> **"legal proceeding"** in addition to having the meaning given to that expression under section 1, includes an action or proceeding for the imposition of punishment by fine, penalty, or imprisonment to enforce any regulation made under an Act of the Legislature and any proceeding before any tribunal, board, or commission;
>
> **"witness"** in addition to the ordinary meaning thereof, includes every person who, in the course of a legal proceeding, is examined *viva voce* for discovery or is cross-examined upon an affidavit made by him, or answers any interrogatories or makes an affidavit as to documents, or is called upon to answer any question or produce any document, whether under oath or not.
>
> **Protection from liability**
>
> 10 Neither
>
> (a) the disclosure of any information or of any document or anything therein, or the submission of any report, statement, memorandum, or recommendation, to any committee to which subsection 9(1) applies, for the purpose of its being used in the course of any study, research, or program carried on by a hospital or any such committee for the purpose of medical education or improvement in medical or hospital care or practice; nor
>
> (b) the disclosure of any information, or of any document or anything therein, that arises out of any such study, research, or program;
>
> raises or creates any liability on the part of the person making the disclosure or submission.

Counsel for some of the families wished to ask some of the members of those standards committees questions about committee proceedings. A considerable amount of time was devoted to argument, and in January 1998, a decision was rendered on the issue. Essentially I ruled that an inquest judge had authority to inquire into proceedings of medical standards committees if their proceedings are relevant to the issues being inquired into. However, I declined to make any such inquiries in view of the lateness of the motion, and the fact that much of the relevant evidence could be otherwise obtained. That decision is filed as part of the record of these proceedings.

IN CAMERA PROCEEDINGS

During the course of hearings some of the witnesses or their counsel asked that certain evidence be heard *in camera*. Provision for doing so is found in section 31 of the *Fatality Inquiries Act*.

> **Inquest open**
>
> 31(1) Subject to subsection (2), an inquest under this Act shall be open to the public.
>
> ***In camera* inquest**

31(2) Where a provincial judge charged with conducting an inquest is of the opinion that testimony to be given or other evidence to be introduced at the inquest includes matters that

(a) involve public security;

(b) are of such a personal nature that, having regard to the circumstances, the privacy of a person would be unreasonably breached; or

(c) relate to professional activities that, having regard to the circumstances, the professional reputation of an individual would be damaged unjustifiably;

the judge may, on application, order that the inquest or a part of the inquest be conducted *in camera*.

Factors for *in camera* inquest

31(3) For the purposes of subsection (2), a provincial judge shall consider the following matters:

(a) the nature of the personal interests or of the professional activities that may be adversely affected by testimony heard or evidence introduced at the inquest;

(b) whether disclosure of all or part of the diagnosis or medical records of the deceased or disclosure of a report of a medical examiner

(i) would result in injury or harm to the mental or physical welfare of a third party,

(ii) would be prejudicial to the interests of a person not involved in the inquest,

(iii) has the approval or consent of the legal representative of the deceased; and

(c) whether conducting the inquest *in camera* would be

(i) in the interests of justice, or

(ii) injurious to the public interest generally.

Application for *in camera* inquest

31(4) A person who

(a) is a Crown attorney or other officer or counsel appointed by the minister to act for the Crown;

(b) is a member of the family of the deceased;

(c) is the legal representative of the deceased;

(d) may be adversely affected, personally or professionally, by evidence given at the inquest; or

(e) is declared by a provincial judge, on application, to be an interested party;

may apply to a provincial judge for an order that an inquest or part of an inquest be conducted *in camera*.

Application *in camera*

31(5) An application under subsection (4) shall be made *in camera*.

Decision final

31(6) An order made under subsection (2) is final and is not subject to judicial review or appeal.

No disclosure of *in camera* evidence

31(7) Subject to subsection 33(2), where an inquest or part of an inquest is conducted *in camera* pursuant to an order made under subsection (2), no person shall disclose or cause to be disclosed to another person testimony heard or evidence introduced *in camera*.

In my opinion, there was merit to the applications made on the grounds set out in the legislation, and from time to time, *in camera* hearings occurred. I have decided that much of the evidence rendered in the *in camera* proceedings need not to be discussed or disclosed in this report. However, even where some of that evidence has been disclosed and discussed, the order made at the time of the *in camera* applications forbidding disclosure of the evidence revealed during those hearings remains in effect. In particular information that might identify children other than those who died in 1994, and whose cases were investigated as part of these proceedings, is not to be disclosed.

DISCLOSURE

In October 1995, hearings were conducted into the question of the disclosure of documents relating to the matters under investigation by this inquest that were in the possession of the Province of Manitoba and the HSC. Disclosure was directed to be made, but for the most part, both the HSC and the Province had voluntarily disclosed a great deal of material. That disclosure resulted in several volumes of documents being marked as exhibits in these proceedings.

Despite the disclosure that was made, it became apparent that there continued to be materials that were in the possession of some of the parties, particularly the HSC, that had not been disclosed as ordered. A considerable amount of material was discovered as the proceedings went on and the witnesses testified. Personal notes, hospital data, memos and correspondence, minutes of meetings and briefing documents were discovered even after disclosure had been ordered. It is conceivable that not every document bearing on the issues under examination was discovered and disclosed during the proceedings. With an institution the size of the HSC and the Department of Health, such an event is entirely possible. However I am satisfied that every effort was made to provide what materials were known to exist, and that any non-disclosure was inadvertent. For that reason I concluded that while any failure to disclose was a cause for concern, it was not enough for any sanctions to be considered.

Despite the lateness of some disclosure, and the fact that not all of the relevant materials may have been provided to the Inquest in a timely manner or at all, the evidence disclosed enough about the events that happened surrounding the program, and in particular the events of 1994, that the facts as they occurred were readily determinable.

THE TAKING OF EVIDENCE

On December 6, 1995, the evidence was heard of Dr. Cameron Ward, a pediatric cardiologist who worked at the Children's Hospital during 1994. Ward had been involved in the care of some of the 12 children, and had held a position with the Variety Children's Heart Centre in 1994. A special hearing was convened in December 1995, as Ward was about to leave Canada for another position in Australia.

The bulk of the evidence, however, began on March 5, 1996. Hearings were held throughout 1996, 1997 and 1998. In total, more than 80 witnesses testified during more than 285 days of hearings over a period of almost three years. Close to 50,000 pages of transcript evidence were produced, and hundreds of documents, eventually exceeding 10,000 pages of material, were filed as exhibits in these proceedings. This is the Final Report of the Inquest.

Chapter 2

PEDIATRIC CARDIAC ISSUES

HOW THE HEART FUNCTIONS, CONGENITAL HEART DEFECTS AND THEIR TREATMENT

THE HUMAN HEART

The heart is a marvellous combination of functional simplicity and systemic complexity. It is, on the one hand, simply a large muscle specifically designed to pump blood through the blood vessels of the body. On the other hand, its importance, while self-evident in one respect (if it does not work, you die) is hidden in many others (if it does not work perfectly, your health can be compromised in less-obvious ways).

The functioning of all other organs and systems within the body depends on an adequate blood supply. One example of this is the brain. Reduction or impairment in its supply of blood can result in a loss of neurological function, a loss of consciousness, or even death. One can, of course, appreciate what a sudden and sustained loss of blood supply can do to someone. But impairment in blood circulation can progress so slowly and over such a long period of time that, while its impact can be serious, its consequences may be difficult to detect. Problems can occur if the heart's ability to function adequately is even slightly impaired. Slow deterioration in cardiac performance can cause an equally slow deterioration in other organ performance. Thus, diagnosing even a minor condition that impairs the heart's performance is important. While one's life may not be immediately threatened by a minor impairment, ultimately one's life can be seriously affected and even shortened by the eventual deterioration and failure of other life-sustaining organs, such as the lungs, the kidneys and the liver. The heart, therefore, plays a central role in sustaining the optimal performance of all other organs and bodily systems. The heart must perform its function in such a way as to enable all other organs of the body to perform their tasks.

The heart muscle even sustains itself. In pumping blood, the blood vessels of the heart, the coronary arteries, are themselves filled with blood. The heart muscle is thereby nourished, allowing it to continue to perform its pumping.

The heart performs a vital balancing act with each contraction. It pushes blood in two major directions—to the lungs and to the body. Blood flows to the lungs through the pulmonary arteries and from the lungs

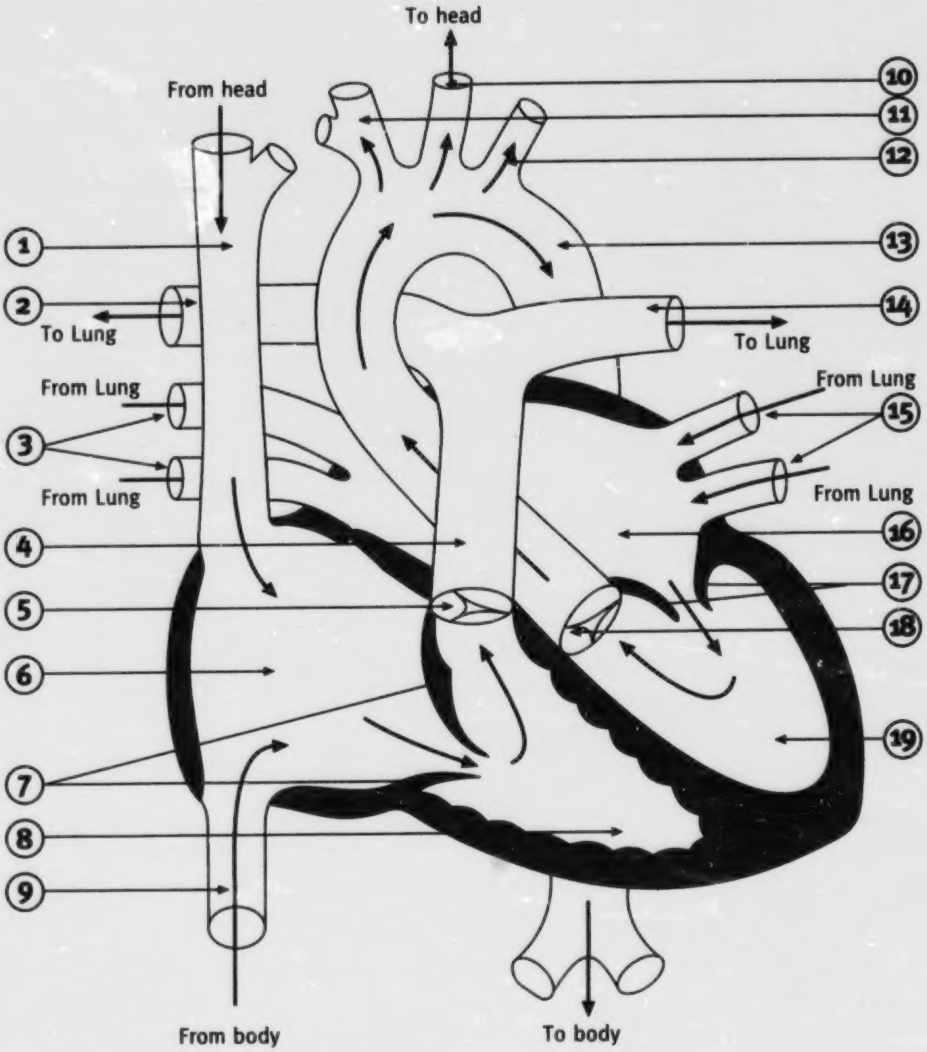
To head
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Diagram 2.1 Normal Heart (with blood flow)

1 - Superior vena cava
2 - Right pulmonary artery
3 - Right pulmonary veins
4 - Pulmonary artery (pulmonary trunk)
5 - Pulmonary valve
6 - Right atrium
7 - Tricuspid valve
8 - Right ventricle
9 - Inferior vena cava
10 - Left common carotid artery
11 - Innominate artery
12 - Left subclavian artery
13 - Aorta
14 - Left pulmonary artery
15 - Left pulmonary veins
16 - Left atrium
17 - Mitral valve
18 - Aortic valve
19 - Left ventricle

through the pulmonary veins, in what is referred to as the pulmonary circulation. Blood flows to the body through arteries and their smaller branches and from the rest of the body in veins and their smaller branches. This is known as the systemic circulation. The amount of blood flow needs to be equal through the left and right sides of the heart and through the systemic and pulmonary circulations.

HOW A NORMAL HEART WORKS

The normal heart consists of four chambers: two upper atria (singular: atrium) and two lower ventricles. The atria are the collecting chambers of the heart, into which blood flows from the body and the lungs. The atria pump blood into the ventricles, although the force of the atrial pumping action is not as strong as that of the ventricles. These are the stronger pumping chambers, responsible for moving blood to the lungs and to the body. Of the two ventricles, the right ventricle is not as strong a pump as is the left ventricle. The right ventricle only pumps blood through the lungs or pulmonary circulation, which has a low resistance and therefore requires less pressure than the left ventricle, which pumps blood around the entire rest of the body. Thus although the amount of flow needs to be equal through the right and left sides of the heart, the pressures are quite different on the two sides.

Blood flows from the body into the right atrium. That blood is 'blue' and is in need of oxygen, because oxygen has been removed from the blood by the body's organs and muscles in the course of blood flow. This blood is referred to as venous blood. It then passes from the right atrium into the right ventricle, which pumps the blood through the pulmonary arteries to the lungs where the blood picks up a fresh supply of oxygen. The oxygenated or 'red' blood then returns to the heart, flowing from the lungs through the pulmonary veins to the left atrium. The oxygenated blood next passes into the left ventricle, from where it is pumped through the aorta to the body.

The heart has three major vessels that bring blood to and take blood from it. The superior vena cava (SVC) and the inferior vena cava (IVC) are the two largest venous vessels that connect to the right atrium. The SVC returns the blood from the head and upper body to the heart to be oxygenated, while the IVC does the same for the lower body. The aorta is the major arterial vessel that takes blood from the heart. The left ventricle pumps all the oxygenated blood through the aorta to the body.

As blood flows through each of the four chambers of the heart, valves open and close in precise sequence. In the normally functioning heart, this allows blood to flow forward into the next chamber and prevents it from flowing backward. If a valve is defective, then blood can sometimes flow backward through it. When blood flows backwards through a valve, this is known as regurgitation.

There are four valves in the heart. The mitral valve and the tricuspid valve separate the heart's upper and lower chambers. The tricuspid valve separates the right atrium from the right ventricle, while the mitral valve separates the left atrium from the left ventricle. These valves are known as the atrioventricular valves.

The pulmonary valve separates the right ventricle from the pulmonary artery, which is the main blood vessel connecting the heart to the lungs. The aortic valve separates the left ventricle from the aorta. It is the closing of all four valves which produces the heart beat sound with its familiar 'lub -dub'.

Diagram 2.2 Heart contracting - atrial contractions
Atria contract, forcing blood out.
Force of blood opens inflow valves and blood enters ventricles.

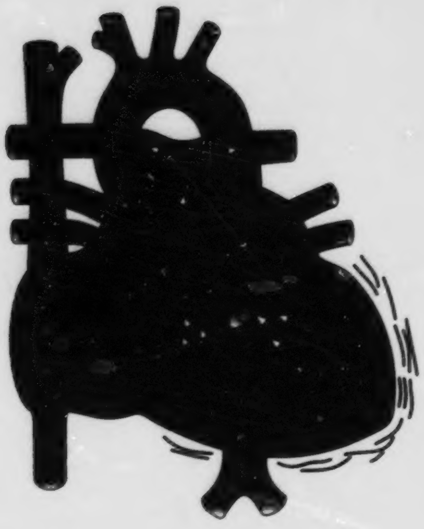

Diagram 2.3 Heart contracting - ventricular contractions
Ventricles contract, forcing blood out.
Force of blood opens outflow valves and closes inflow valves.

When heard with a stethoscope, heart murmurs sound like soft whooshing noises that follow or replace the normal sounds of the heart's action. Murmurs may indicate that blood is leaking through an imperfectly closed valve and may signal the presence of a serious heart problem.

The contractions of the heart are actually more complex than the simple squeezing of a bag. In effect, the heart contracts in rhythm, with the left ventricle contracting slightly ahead of the right ventricle. These contractions occur so closely together that one can think of them as one contraction, but that is not actually the case.

The wall of the heart consists of three distinct layers—the epicardium (outer layer), the myocardium (middle layer) and the endocardium (inner layer). The myocardium actually causes the heart to contract, as its muscle fibres create a wringing movement that efficiently squeezes blood from the heart with each beat. The thickness of the myocardium varies according to the pressure generated to move blood to its destination. Thus the myocardium of the left ventricle is thicker than the myocardium of the right ventricle. The endocardium lines the cavities of the heart, covering the valves, small (papillary) muscles inside the heart and structures called chordae tendinae. (These are fibromuscular structures extending from the papillary muscles to the edge of the mitral and tricuspid valves.)

The volume of blood expelled by the heart is referred to as the cardiac output. This is usually calculated on the basis of the volume of blood expelled with each contraction of the heart (or stroke volume), multiplied by the number of times that the heart beats each minute.

Blood pressure is a measure of the force that results from the heart's pumping action. The highest (systolic) pressure occurs during contraction of the ventricles; the lowest (diastolic) pressure occurs during ventricular relaxation. When the blood pressure is too low, the patient is said to have hypotension. When blood pressure is too high, the patient is said to have hypertension.

The heart is suspended in a membranous sac called the pericardium. The fibrous pericardium (the strong outer portion of the sac) is firmly attached to the diaphragm beneath it, to the membrane lining the chest on each side and to the sternum (or breast bone) in front. The heart is covered by the visceral pericardium or epicardium. Between the heart and the epicardium lies the pericardial cavity, which is normally filled with a very small amount of pericardial fluid.

The pericardium can become irritated or inflamed following surgery. This condition is called pericarditis. This can be accompanied by an increase of fluid in the pericardial sac. If this fluid accumulates rapidly or in great amounts, the heart can become compressed by the fluid, a state called cardiac tamponade. The heart then has less ability to fill with blood and there is less cardiac output. Severe cardiac tamponade can cause a shock-like state that may be fatal. In such cases it is necessary to remove the fluid.

CONGENITAL HEART DISEASE

In the case of children, most heart problems are congenital—that is, they are problems the child is born with, as opposed to problems that arise from lifestyle or later activities. Congenital heart problems usually stem from abnormalities or defects in the structure of the heart. In such cases, the heart will not have formed properly. (Another term for a congenital heart defect is a 'lesion.') Some defects require treatment, while others will lessen in severity as the child grows and may not have to be treated.

Some pediatric cardiac surgical procedures can produce as close to a normal heart as is possible (for example, repairs of atrial or ventricular septal defects). Other operations cannot make the heart normal. The most that cardiac surgery can do for children with some congenital heart defects or lesions is to correct the blood circulation to ensure that most of the 'blue blood' (deoxygenated blood) goes to the lungs and most of the 'red blood' (oxygenated blood) goes to the body. However, the heart's structure post-operatively can be far from normal. Therefore, while corrective heart surgery can allow for a significant improvement in lifestyle, it is not always usually curative in the sense of making the heart normal.

VENTRICULAR FAILURE

One of the main threats that children with these heart defects face is from heart failure. Heart failure occurs when the pumping capability of the heart is impaired and the ventricles are unable to pump an adequate volume of blood to the body and/or the lungs. This can affect either the left ventricle or the right ventricle or both (as in biventricular failure).

Left ventricular failure

With left-sided heart failure, blood backs up in the left ventricle and then progressively into the left atrium and into the lungs. Fluid will then build up in the lungs, making it more difficult for the blood to pick up oxygen. The patient will often be short of breath and breathe rapidly but shallowly, and may cough. Also, because the left ventricle is not pumping enough oxygenated blood out to the body, the skin may be cool and appear bluish, and pulses will feel weak. There may be insufficient blood flow and oxygen delivery to the organs, which may also start to fail. For example, the kidneys may start to produce less urine and the patient may retain fluid and appear to gain weight.

Right ventricular failure

With right-sided heart failure, fluid builds up in the right ventricle, and then backs up into the right atrium and into the great veins (the IVC and the SVC). This leads to swelling, which may be seen in the ankles and across the backs of the hands and feet. The liver also often becomes swollen and enlarges so that it can be felt below the ribs of the right side of the chest.

Biventricular failure

Sometimes left-sided heart failure can lead to failure of the right side of the heart, as blood backs up through the lungs and into the right side of the heart. This places a strain on the right heart, which may then also fail.

SHUNTING

Shunting is the term applied when blood from the left and right sides of the circulation becomes mixed. The site at which shunting occurs and the amount of mixing will determine how much oxygenated blood is supplied to the tissues of the body. Normally, shunting is primarily from the side with the higher pressure to the side with the lower pressure: that is, from left to right. This may lead to changes in the right side, which then develops an increase in resistance to flow. The result is that the pressures on the left and right sides then become equal. This situation may become irreversible, preventing surgical corrections from being successfully undertaken.

PEDIATRIC HEART DEFECTS AND THEIR TREATMENT

The following section outlines the major heart defects that were diagnosed in the children whose deaths are under investigation in this Inquest.

PATENT DUCTUS ARTERIOSUS (PDA)

One of the heart problems diagnosed in these children was a patent ductus arteriosus. The ductus arteriosus is a blood vessel that is present in all babies before they are born. While in the womb, the lungs of the fetus cannot provide oxygen to the fetus's blood. Instead, the fetus receives its oxygen from its mother, through the umbilical cord. Because of that, the fetal lungs do not need to receive the volume of blood flow that will be required after birth. The ductus arteriosus connects the pulmonary artery to the aorta, allowing blood to bypass the lungs. Normally the ductus arteriosus closes on its own within a few days of birth as the lungs begin to strengthen and provide the body with the oxygen it requires. Once it is closed it is referred to as a ligamentum arteriosus.

Occasionally, the ductus may not close on its own and remains open (or, in medical terms, patent). This condition is called a patent ductus arteriosus (PDA). In some babies, a procedure known as a PDA ligation must be performed to close (or, in medical terms, to ligate) the PDA and prevent blood from flowing through it. Otherwise, if the ductus arteriosus remains patent, the newborn may develop congestive heart failure from the increased pulmonary blood flow.

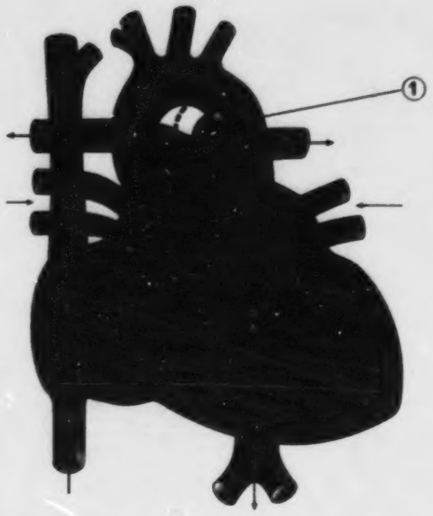

Diagram 2.4 Patent ductus arteriosus

1 – open or patent ductus arteriosus

The shunt or abnormal flow is from aorta to pulmonary artery as indicated by the shaded red arrow.

The diagrams illustrating pediatric heart defects demonstrate general blood flow, but are not representative of any specific point in the heart's cycle.

Sometimes closure of the ductus is not a positive development if the baby suffers from other defects that prevent adequate blood flow to either the lungs or body. Then the patent ductus may provide an alternative and necessary route for blood flow. In these babies, a drug (prostaglandin) can be given to keep the ductus open.

SEPTAL DEFECTS

The most common pediatric cardiac problems result from defects in the wall separating the right and left sides of the heart. The wall is called the septum, while the defects are referred to as septal defects. The wall between the atria is called the atrial septum and the wall between the ventricles is called the ventricular septum. A defect in the wall between the atria is referred to as an ASD, or atrial septal defect, and a defect in the wall between the ventricles is called a VSD, or ventricular septal defect. The defect can range from a small hole in the septum to a significant portion of the septum actually being missing. When there is such a defect, shunting can occur.

If blood flows from the right side of the heart to the left, the child may appear blue because of the lack of oxygen in the blood. The medical term for this reduced oxygen supply is cyanosis, and a baby with blue colouring is described as being cyanotic. With some septal defects, blood may actually flow back and forth between the right and left sides of the heart.

Some VSDs occur at a higher point on the septal wall, where the septum is thinner. These are referred to as perimembranous VSDs. Those VSDs that occur at a lower point on the septal wall, where the septum is

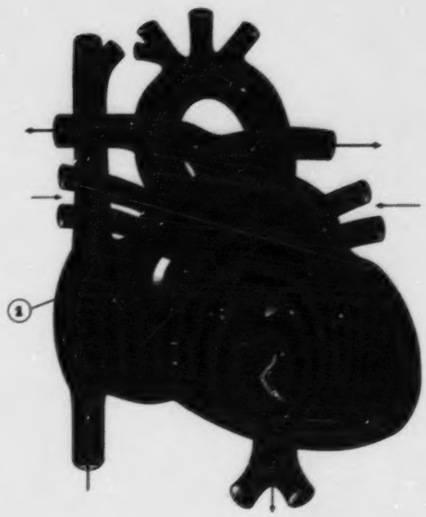

Diagram 2.5 Atrial septal defect (ASD)

1 – atrial septal defect

The shunt or abnormal flow is from left atrium to right atrium as indicated by the shaded red arrow.

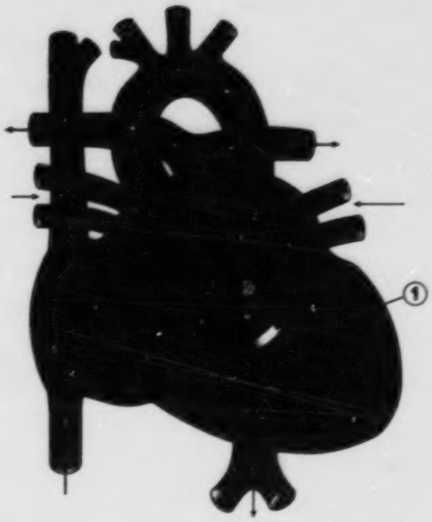

Diagram 2.6 Ventricular septal defect (VSD)

1 – ventricular septal defect

The shunt or abnormal flow is from left ventricle to right ventricle as indicated by the shaded red arrow.

thicker, are called muscular VSDs, which may be single or multiple. Other VSDs occur just below the aortic valve and are referred to as subaortic VSDs.

Some ASDs and VSDs can heal or close on their own, but in a significant number of patients, surgery is required to repair them. Repairs can take the form of a suture (or stitch) being used to close the opening if it is small enough, or a patch actually being sewn over the opening in the case of larger defects. Such patches are usually made of the patient's own pericardium or inert material such as teflon. Pericardial tissue is preferred, since it stands a smaller chance of infection or rejection and can usually grow along with the heart itself.

TETRALOGY OF FALLOT

Tetralogy of Fallot involves four defects within the heart. The first is a hole in the ventricular septum or a VSD. Second, the aorta, which is normally attached to the left ventricle, is wrongly positioned overtop the ventricular septum (and is termed an overriding aorta). Third, there is thickening (in medical terms, hypertrophy) of the muscle of the right ventricle (referred to as right ventricular hypertrophy). The fourth condition is a partial or complete obstruction of blood flow from the right ventricle (also termed RVOT—right ventricular outflow tract obstruction). This most often results from pulmonary narrowing (or, in medical terms, stenosis).

Pulmonary stenosis is a narrowing of the vessels carrying blood from the right ventricle to the lungs. This narrowing is caused by an underdevelopment of the area around the lung valve and along the pulmonary arteries, and can range from a blockage at the valve to thickening below the valve. There can also be narrowing of the pulmonary artery above the valve, and the vessel can narrow into both of the branches that go to the lungs.

To provide relief for the lack of blood flow created by the pulmonary stenosis, it is usually necessary to insert a small tube as an artificial shunt. This shunt then connects the aorta (or one of its branches, such as the subclavian artery) to one of the pulmonary arteries. The best size for the shunt will depend on the size of the patient, as well as the specific structure of the patient's heart and blood vessels.

Such shunts are often referred to as Blalock-Taussig shunts, after the surgeons who developed them, and are used in a variety of pediatric cardiac procedures. Depending on the artery to which the shunt is connected, they are known as either classic or modified Blalock-Taussig shunts.

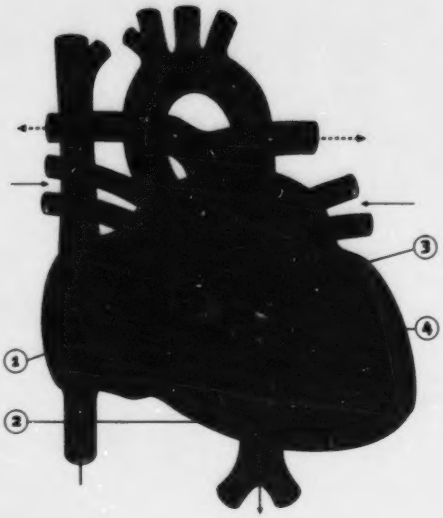

Diagram 2.7 Tetralogy of Fallot

1 – pulmonary stenosis (a form of right ventricular outflow tract obstruction)
2 – right ventricular hypertrophy
3 – overriding aorta
4 – ventricular septal defect

The degree of pulmonary stenosis controls the flow patterns. The shaded blue arrows show blue blood mixing with red blood. The broken white arrows indicate diminished blood flow through the pulmonary artery.

Children with Tetralogy of Fallot are often referred to as Tet babies. Some children with this condition also suffer from weight loss or fail to gain weight (known medically as failure to thrive). Other Tet babies suffer Tet spells or periods when they are extremely cyanotic. Symptoms include anxiety, air hunger, respiratory distress, increasing cyanosis and an altered level of consciousness. The symptoms are most often brought on by activity. Tet spells usually indicate an urgent need for repair of the heart defect.

The operation to correct Tetralogy of Fallot consists of removing the outflow tract obstruction and patching the VSD. Care must be taken not to damage the heart's electrical conduction system because of the nature of the operation. Damage to the heart's electrical conduction system can interfere with the heart's ability to beat properly.

Most often, complete correction of the lesions is performed, even in newborns. Palliative procedures are reserved for those patients with extremely abnormal hearts, such as those with severe underdevelopment (hypoplasia) of the pulmonary arteries and certain abnormalities of the coronary arteries. (A palliative procedure is one that alleviates the current problem but is not a definitive repair and does not usually offer a long-term good outcome.)

ATRIOVENTRICULAR CANAL DEFECT

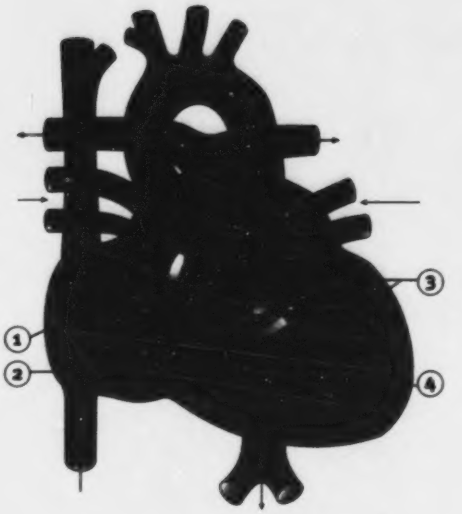

Diagram 2.8 Atrioventricular (AV) canal defect

1 – atrial septal defect
2 – abnormal tricuspid valve
3 – abnormal mitral valve
4 – ventricular septal defect

The shunt or abnormal flow is from left atrium to right atrium, left ventricle to right ventricle (as indicated by the shaded red arrows). Tricuspid and mitral valve regurgitation occurs as a result of the abnormal tricuspid and mitral valves.

Atrioventricular (AV) canal defect is a large hole in the centre of the heart. The defect is situated where the septal wall between the upper chambers (atria) joins the septal wall between the lower chambers (ventricles). In addition, the tricuspid and mitral valves (the atrioventricular valves), which normally separate the heart's upper and lower chambers, are not formed as individual valves. Instead, one large valve bridges the defect.

Complete AV canal defect, also known as an atrioventricular septal defect or endocardial cushion defect, is often associated with other cardiac defects, such as Tetralogy of Fallot. The complete AV canal defect is commonly found in children with Down's syndrome. An incomplete or partial form of AV canal defect, known as an ostium primum atrial septal defect, involves only the atrial septum.

The AV canal defect lets some of the oxygen-rich blood from the heart's left side pass (or shunt) back into the heart's right side. There, the oxygen-rich blood mixes with the oxygen-poor venous blood from the body and is sent back to the lungs. This results in the heart pumping an extra amount of blood and working harder than it should. In time, the extra work causes the heart to enlarge. There is also an associated increase in the pressure in the pulmonary artery, which may cause problems.

With complete AV canal defects, signs and symptoms occur early in infancy. These usually include abnormal heart sounds, congestive heart failure, intermittent cyanosis, respiratory infections, poor feeding and inadequate weight gain.

In a baby with severe symptoms or high pulmonary artery pressure, surgery must usually be done in infancy. The surgeon closes the hole with one or two patches. The single valve is then divided between the atria and the ventricles to make two separate valves. Again, care must be taken not to damage the heart's electrical conduction system.

COARCTATION OF THE AORTA

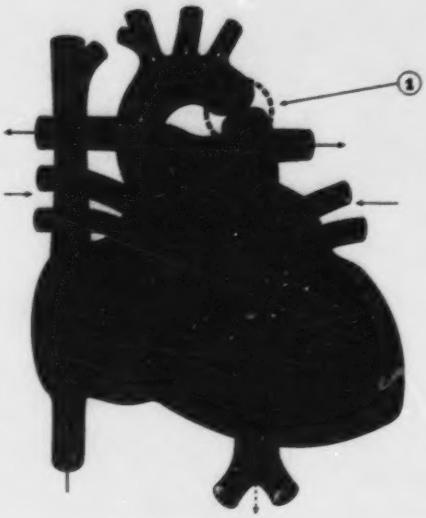

Diagram 2.9 Coarctation of the aorta

1 – pinched or coarcted aorta

Flow patterns are normal but are reduced below the coarctation. Blood pressure is increased in vessels leaving the aorta above the coarctation. The broken white arrow indicates diminished blood flow through the aorta.

In the normal heart, blood flows to the body through the aorta, which connects to the left ventricle and arches over the top of the heart. In coarctation of the aorta, the aorta is pinched (in medical terms, coarcted) at a point somewhere along its length. This pinching restricts blood flow from the heart to the rest of the body. Often, the baby also has other heart defects, such as a narrowing of the aortic arch (in medical terms, transverse aortic arch hypoplasia).

Usually no symptoms are apparent at birth, but can develop within a week of birth with the closure of the ductus arteriosus. The possible consequences of this condition are poor feeding, an enlarged heart, an enlarged liver and congestive heart failure. Blood pressure also increases above the constriction.

Timing of surgery depends on the degree of coarctation. Surgery may be delayed with mild coarctation (which sometimes is not detected until adolescence). However, if a baby develops congestive heart failure or high blood pressure, early surgery is usually required. A baby with severe coarctation should have early surgery to prevent long-term high blood pressure.

The coarctation can be repaired in a number of ways without opening the heart. The surgeon can remove the narrowed part of the aorta and sew the ends together, thereby creating an anastomosis. (An anastomosis is the surgical formation of a connection between two normally distinct structures.) Alternatively, the surgeon can cut the narrowed section open and sew a patch over the opening.

INTERRUPTED AORTIC ARCH

In this condition, the aorta does not develop completely in the area of the arch. As a result, the aorta is divided into two parts that are not connected to each other. This prevents the flow of blood through the aorta. Because blood flow through the aorta is blocked, the blood supply to the lower body is compromised. At birth, the open ductus arteriosus allows blood to flow from the right ventricle to the lower body. There are often other coexisting heart defects, such as a VSD.

Interrupted aortic arch is usually diagnosed when the ductus arteriosus begins to close. With decreasing circulation to the lower body, serious damage can occur to the liver, kidneys and intestines. Prostaglandin is given to keep the ductus arteriosus open until surgery is performed, usually as soon after birth as possible.

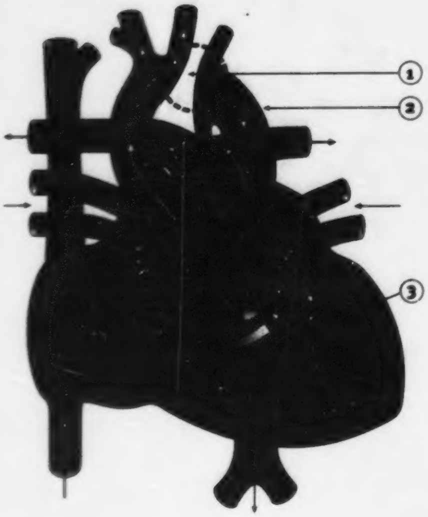

Diagram 2.10 Interrupted aortic arch

1 – interruption of aortic arch

2 – descending aorta connected to pulmonary artery by large patent ductus arteriosus

3 – ventricular septal defect

Flow patterns are normal to the upper body. However, there is no flow of oxygenated blood to the lower body unless there exist, as in this drawing, shunts such as a ventricular septal defect that allows oxygenated blood into the pulmonary artery, and a patent ductus arteriosus that allows the partially oxygenated blood to travel from the pulmonary artery to the descending aorta (as indicated by the broken white arrow).

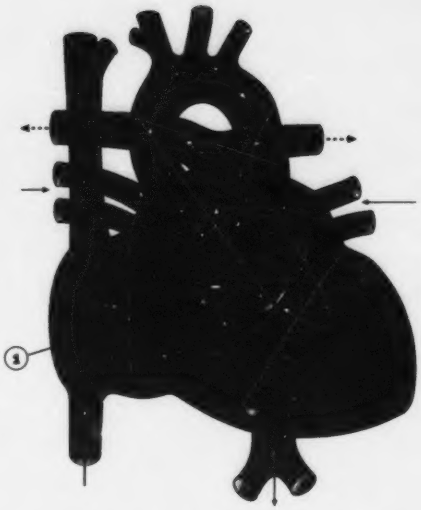

Diagram 2.11 Pulmonary stenosis (valvular)

1 – narrowed pulmonary valve

Blood flow patterns are normal but blood flow through the pulmonary artery is reduced as indicated by the broken white arrows.

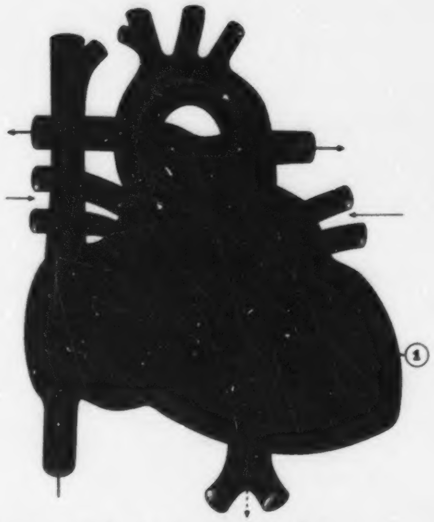

Diagram 2.12 Aortic stenosis (valvular)

1 – narrowed aortic valve

Flow patterns are normal but blood flow to the aorta is reduced as indicated by the broken white arrows.

Most often a one-stage repair is undertaken, patching the arch or connecting the two ends of the aortic arch together, closing any VSD, and tying off and dividing the ductus arteriosus into two parts.

PULMONARY STENOSIS AND AORTIC STENOSIS

Any one of the heart's valves may suffer from narrowing (or stenosis). This narrowing, which can occur at, above or below the valve, can block blood flow.

In pulmonary stenosis, the area around the pulmonary valve can become blocked or the blood vessel beyond the valve can become narrowed, causing the right ventricle to have to pump harder to get blood past the blockage to the pulmonary artery. If the stenosis is severe, there will be a lack of blood flow to the lungs and the baby can become cyanotic. The condition requires treatment when the pressure in the right ventricle is high.

In aortic stenosis, the aortic valve also can become narrowed, requiring the left ventricle to pump harder to get blood past the blockage to the aorta and out to the body. The normal aortic valve has three cusps or leaflets and is described as tricuspid. In contrast, a stenotic aortic valve may have only two cusps (bicuspid) or even one cusp (unicuspid). The cusps in a stenotic valve are usually thick and stiff.

One treatment for stenosis is to insert a special catheter containing a balloon through the valve. The balloon is then inflated, stretching the valve open. This procedure is known as a balloon valvuloplasty and is performed during a cardiac catheterization (a procedure that is discussed in the following chapter). In most children, a valvuloplasty may be sufficient to alleviate the stenosis. In other children, surgery may be needed.

TRICUSPID ATRESIA

Atresia means the absence or closure of a normal body opening or tubular structure. In tricuspid atresia, the tricuspid valve is missing, preventing blood from flowing from the right atrium into the right ventricle. Because the right ventricle has no blood to pump, it remains small and underdeveloped.

In this condition, the child's survival depends on the presence of two septal defects: an atrial septal defect (ASD) and a ventricular septal defect (VSD). The ASD allows the venous blood to flow from the right atrium into the left atrium. There, venous blood mixes with oxygen-rich blood from the lungs, flows to the left ventricle, into the aorta and out to the body. The rest of the mixture is pumped from the left ventricle through the VSD into the right ventricle, and on through the pulmonary artery back to the lungs.

Sometimes the baby will also have other cardiac defects. These include transposition of the great arteries (to be discussed later), coarctation of the aorta or pulmonary atresia.

The majority of babies with tricuspid atresia are cyanotic at birth. These children will require surgery to place a tube (known in medical terms as a shunt), which will provide an increase in blood flow to the lungs.

Other children have too much blood flowing to the lungs and need a procedure called pulmonary artery banding. In this procedure, the surgeon places a band around the pulmonary artery to narrow it, and to reduce the blood flow and resultant high pressure in the lungs.

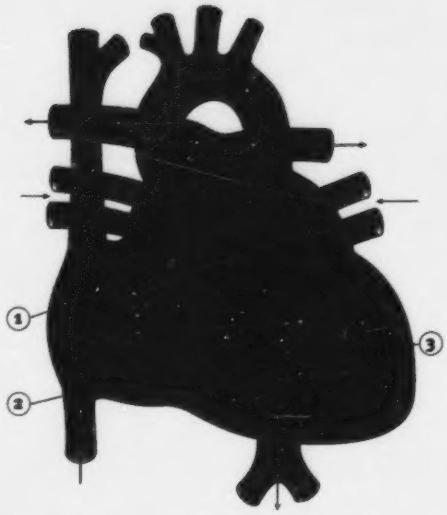

Diagram 2.13 Tricuspid atresia (showing no opening between the right atrium and ventricle)

1 – atrial septal defect

2 – absent tricuspid valve

3 – ventricular septal defect

Blood is shunted through an atrial septal defect to the left atrium and through the ventricular septal defect to the pulmonary artery. The shaded arrows indicate mixing of the blood.

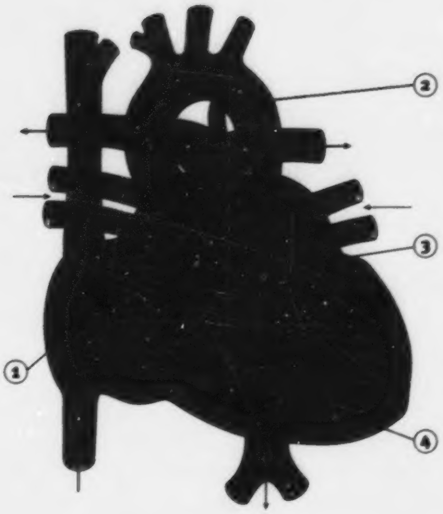

Diagram 2.14 Pulmonary atresia

1 – atrial septal defect

2 – patent ductus arteriosus

3 – absent pulmonary valve

4 – hypoplastic right ventricle

Abnormal blood flow (as indicated by the shaded blue arrow) is from the right atrium and right ventricle through an atrial septal defect to the left side of the heart. Blood can reach the pulmonary arteries only through a patent ductus arteriosus.

In other children the surgeon connects the right atrium and the pulmonary artery and closes the ASD. This procedure is known as a Fontan, named after the doctor who first perfected the procedure. The Fontan repair allows blood to flow passively from the right atrium to the pulmonary circulation without being pumped by the right ventricle. The functioning of this repair relies totally on the preservation of a low resistance in the pulmonary arterial vessels.

PULMONARY ATRESIA

In the condition known as pulmonary atresia, no pulmonary valve exists. Blood is therefore unable to flow from the right ventricle into the pulmonary artery and onward to the lungs. As a further result, the right ventricle usually remains hypoplastic. In addition, the tricuspid valve or right atrioventricular valve is often poorly developed.

With pulmonary atresia, the only means of getting blood flow to the lungs is through the ductus arteriosus, which connects the pulmonary artery and the aorta. The infant is usually cyanotic.

Blood returning to the right atrium and right ventricle therefore needs to shunt across to the left side of the circulation, through either an ASD or a patent foramen ovale. The foramen ovale is a natural septal opening in the fetal heart that allows blood to flow between the atria. In most newborns this opening closes at birth. Failure of the foramen ovale to close results in a type of atrial septal defect, known as a patent foramen ovale (PFO). Where there is an ASD or a PFO, blood leaves the right atrium and mixes with the oxygen-rich blood in the left atrium. This blood is then pumped by the left ventricle into the aorta and out to the body.

A further problem arises when the ductus arteriosus closes, causing severe cyanosis. The infant is then usually given prostaglandin to keep the ductus arteriosus open. As a palliative measure, a surgeon may create a shunt between the pulmonary artery and the aorta to increase blood flow to the lungs. If the right ventricle is too small to be effective as a pump, a Fontan procedure is performed later, connecting the right atrium directly to the pulmonary artery. The ASD or PFO is also closed to relieve the cyanosis.

TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION

The pulmonary veins usually connect to the left atrium. However, in total anomalous pulmonary venous connection (TAPVC), there is no direct connection between any pulmonary vein and the left atrium. The pulmonary veins that normally bring oxygen-rich blood back from the lung are not connected to the left atrium. Instead, they drain through abnormal connections to the right atrium.

In the right atrium, the oxygen-rich blood from the pulmonary veins mixes with the oxygen-poor venous blood from the body. Some of this mixture then passes through an atrial septal defect or a PFO into the left atrium. The result is that the blood flowing to the body is poorly oxygenated. The rest of the poorly oxygenated mixture flows through the right ventricle into the pulmonary artery and on to the lungs.

Both congestive heart failure and pulmonary artery hypertension may develop. Signs of these may appear soon after birth and vary in severity. They include a lethargic appearance, pallor or cyanosis, poor feeding and weight loss. TAPVC is usually repaired in early infancy or when the abnormality is diagnosed. Surgical repair involves reconnecting the pulmonary veins to the left atrium and closing the atrial septal defect or PFO.

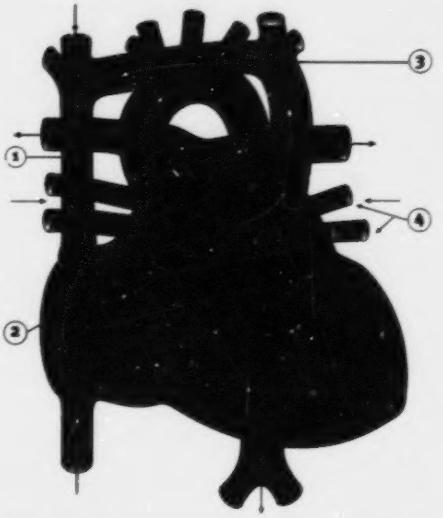

Diagram 2.15 Total anomalous pulmonary venous connection (showing pulmonary veins connected to the left innominate vein)

1 – superior vena cava
2 – atrial septal defect
3 – left innominate vein
4 – pulmonary veins

Oxygenated blood returning from the lungs is routed back into the superior vena cava, rather than the left atrium. The presence of an atrial septal defect is necessary to allow partially oxygenated blood to reach the left side of the heart.

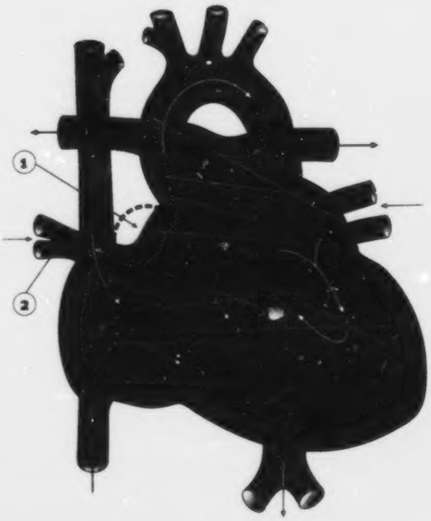

Diagram 2.16 Partial anomalous pulmonary venous drainage

1 – location where right pulmonary veins normally enter left atrium

2 – right pulmonary veins entering right atrium

Oxygenated blood flows from the right pulmonary veins into the right atrium instead of into the left atrium.

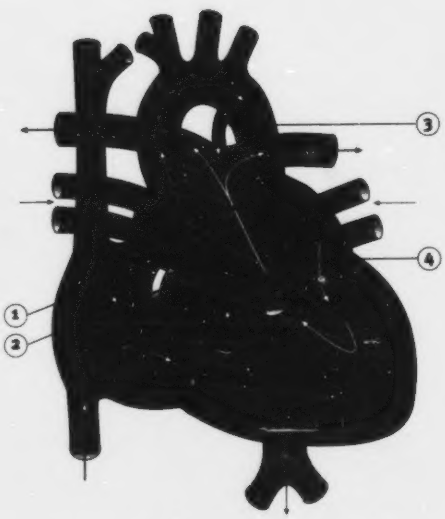

Diagram 2.17 Transposition of the great arteries

1 – atrial septal defect or patent foramen ovale

2 – aorta connected to right ventricle

3 – patent ductus arteriosus

4 – pulmonary artery connected to left ventricle

With the presence of an atrial septal defect, two parallel blood flows exist, with one recirculating oxygenated blood and one recirculating de-oxygenated blood. As shown in this diagram, mixing occurs via the atrial septal defect.

PARTIAL ANOMALOUS PULMONARY VENOUS DRAINAGE

Partial anomalous pulmonary venous drainage (PAPVD) exists when one or more of the pulmonary veins drain to the left atrium while the other vein is connected to the right atrium. The result is that some oxygen-rich blood is returned to the right atrium and mixes with venous blood, and is then returned to the lungs instead of flowing out of the heart to the body. The result of this anomaly is that the right side of the heart must work harder. PAPVD is often associated with an ASD or with more complex cardiac defects.

Surgery is needed when the child has increasing pulmonary pressures or develops congestive heart failure. Depending on the complexity of the PAPVD, surgery usually involves connecting the pulmonary veins to the left atrium.

TRANSPOSITION OF THE GREAT ARTERIES

In transposition of the great arteries (also sometimes called transposition of the great vessels), the aorta and the pulmonary artery (the great arteries) are each connected to the wrong ventricles. The aorta is connected to the right ventricle, so that venous blood is carried to the body instead of to the lungs. The pulmonary artery is attached to the left ventricle, so that oxygen-rich blood is carried back to the lungs instead of to the body.

Newborns with transposition survive only if they have one or more connections that let oxygen-rich blood reach the body. These connections may be in the form of a hole between the two ventricles, a patent foramen ovale or a patent ductus arteriosus. Most babies born with transposition are extremely blue soon after birth because their bodies are not receiving enough oxygenated blood.

In order to immediately improve the body's oxygen supply, prostaglandin is given to keep the ductus arteriosus open. It is also possible to enlarge the patent foramen ovale by inflating a small balloon during a heart catheter procedure. This is known as a balloon atrial septostomy and allows more mixing between the right and left sides of the circulation.

A common surgical procedure for treating transposition is known as an arterial switch. In this operation, the great arteries are disconnected from the ventricles to which they are attached at birth and are reconnected to the appropriate ventricles. The pulmonary artery is connected to the right ventricle, while the aorta is connected to the left ventricle. The coronary arteries are also re-implanted. Depending on the condition of the baby, this procedure may be done in the first few weeks after birth. The repair is more complicated if there is also a large VSD or other defects. An arterial switch operation is considered a high-risk procedure.

DOUBLE OUTLET RIGHT VENTRICLE

Double outlet right ventricle (DORV) is a condition in which both the pulmonary artery and the aorta connect to the right ventricle. DORVs are usually accompanied by one of a number of ventricular septal defects. The three types of VSDs most likely to occur with DORV are subaortic VSD (the defect is located beneath the aortic valve), subpulmonary VSD (the defect is located beneath the pulmonary valve) and doubly committed VSD (the defect is located within the septal band and immediately beneath the leaflets of the aortic and pulmonary valves). Sometimes the baby will have other associated cardiac defects.

Symptoms tend to occur early in life, often within days of birth. The two major symptoms are congestive heart failure and cyanosis. In some cases, cyanosis can become severe because of reduced pulmonary blood flow.

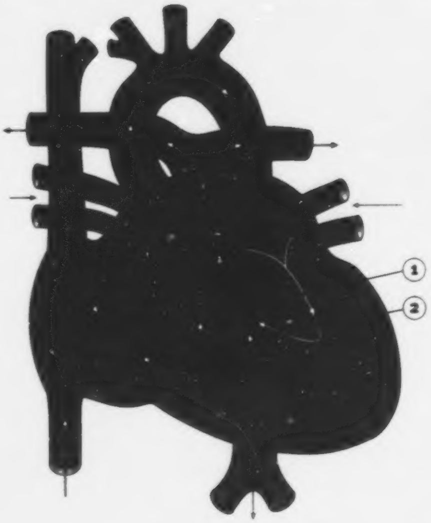

Diagram 2.18 Double outlet right ventricle

1 – overriding aorta

2 – ventricular septal defect

De-oxygenated blood enters the aorta from the right ventricle and is returned to the body.

The goal of the surgical treatment of DORV is a complete anatomic repair. The left ventricle is connected to the aorta, the right ventricle is connected to the pulmonary artery and the VSD is closed. Usually a complete repair is undertaken at as early an age as possible.

HYPOPLASTIC LEFT HEART SYNDROME

Hypoplastic left heart syndrome (HLHS) refers to the grouping of certain congenital cardiac defects. The main characteristics are the marked hypoplasia (underdevelopment) or even absence of the left ventricle and severe hypoplasia of the aorta. Often a localized pinching (coarctation) of the aorta is also present. The main pulmonary artery is enlarged, and gives rise to a large ductus arteriosus. This allows blood to flow from

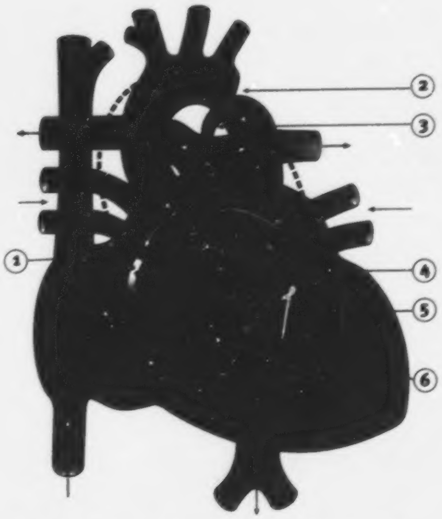

Diagram 2.19 Hypoplastic left heart syndrome (HLHS)

1 – patent foramen ovale
2 – pinched aorta
3 – patent ductus arteriosus
4 – narrowed aorta
5 – hypoplastic left ventricle
6 – aortic atresia

The lack of a developed left ventricle, plus the aortic coarctation leads to reversed blood flow through the aorta. Partially oxygenated blood reaches the aorta after travelling through the patent foramen ovale, up the pulmonary trunk and through the patent ductus arteriosus. The major blood flow to the systemic circulation is through the PDA.

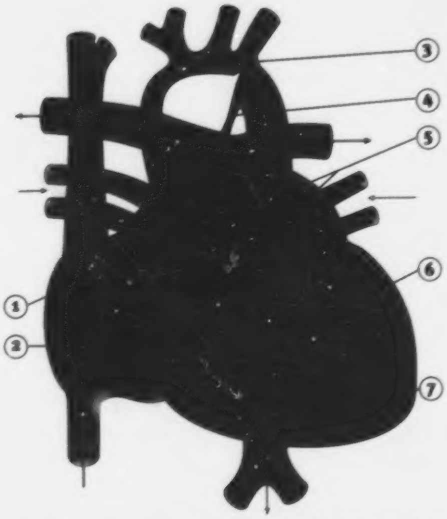

Diagram 2.20 Functional hypoplastic left heart syndrome

1 – patent foramen ovale or atrial septal defect secundum
2 – tricuspid valve atresia
3 – hypoplastic aortic arch
4 – patent ductus arteriosus
5 – transposition of the great arteries
6 – restrictive muscular ventricular septal defect
7 – hypoplastic right ventricle

De-oxygenated blood flows from the right atrium through an atrial septal defect into the left atrium. There it mixes with oxygenated blood returning from the lungs. A portion of this blood flows from the left ventricle up the pulmonary trunk to the lungs and through the patent ductus arteriosus to the body. Another portion of this blood flows through a ventricular septal defect, and is pumped by the hypoplastic right ventricle up the aorta.

the right ventricle into the aorta and out to the body. Other characteristics of HLHS often include a combination of aortic and mitral stenosis or aortic and mitral atresia.

HLHS is also used to describe cases in which the right ventricle is hypoplastic and the child also suffers from transposition of the great arteries. In such cases the hypoplastic right heart pumps into the same artery that the left ventricle normally pumps blood through, and therefore the circulation is the same as in HLHS. This is sometimes referred to as functional HLHS.

HLHS is a severe form of congenital heart disease. Without surgical intervention, HLHS is fatal. Infants are often diagnosed within 24 to 48 hours of birth. Symptoms appear when the ductus arteriosus begins to close.

There are three options for treating these children: supportive care until death occurs, staged reconstruction of the heart, or a heart transplant.

Supportive care

Before surgical treatment was developed, at least 90 per cent of infants with this condition died by the age of one month. Even today, some infants are not candidates for surgical therapy. For these infants, supportive care is the only option. Exactly what this care entails will depend on the condition of the infant, but would likely include assistance with breathing, the provision of fluids and management of pain.

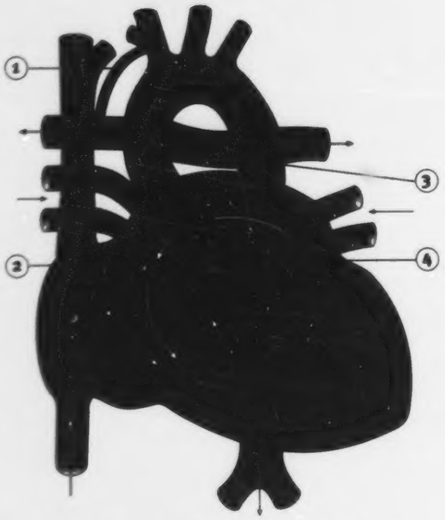

Diagram 2.21 Stage 1 of hypoplastic left heart syndrome reconstruction (Norwood)

1 – Blalock-Taussig shunt (temporary)
2 – atrial septum removed
3 – patch where pulmonary trunk is disconnected from left and right pulmonary artery
4 – aorta and pulmonary trunk anastomosed together and the aorta made larger

Blood flows through the anastomosed aorta and pulmonary trunk to the aortic arch. A shunt connects the aorta to the pulmonary arteries, providing the lungs with blood to oxygenate.

Reconstruction of the heart

Staged reconstruction is the treatment of choice for hypoplastic left heart syndrome. Reconstruction takes place in three stages.

The first stage, known as a Norwood operation, is undertaken as soon as possible after birth. This stage calls for a homograft[1] to be used to enlarge the rudimentary aortic arch and then join it to the pulmonary trunk. This is known as an anastomosis. The pulmonary trunk will have been disconnected from the left and right pulmonary arteries. The newly created blood vessel functions as the

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[1] A homograft is a graft of tissue between animals of the same species. In the case of humans, a homograft comes from a tissue donor. A homograft is in contrast to an autograft, which is a graft of tissue transferred from another part of the patient's body. With pulmonary homografts, the pulmonary artery is removed from a tissue donor shortly after death. The pulmonary homograft is prepared and stored indefinitely at –70 degrees Celsius in liquid nitrogen until needed, when it is thawed and prepared under sterile conditions.)

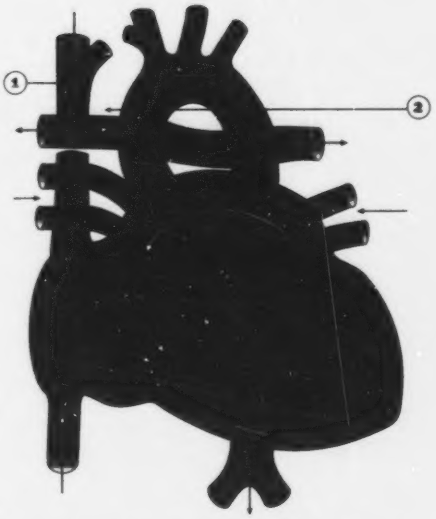

Diagram 2.22 Stage 2 of hypoplastic left heart syndrome reconstruction

1 – superior vena cava connected to pulmonary artery

2 – takedown of Blalock-Taussig shunt

De-oxygenated blood from the superior vena cava is routed directly to the lungs. A mix of oxygenated and de-oxygenated blood is sent to the body through the anastomosed aorta and pulmonary trunk.

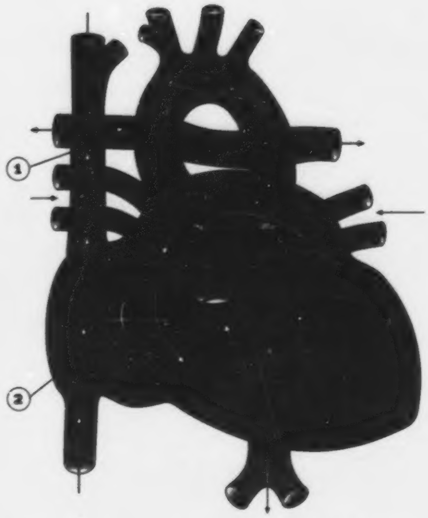

Diagram 2.23 Stage 3 of hypoplastic left heart syndrome reconstruction (Fenestrated Fontan)

1 – conduit joining inferior vena cava and superior vena cava to right pulmonary artery

2 – artificial wall containing small hole (to separate blue blood from red blood in atria and to channel blue blood from lower body to pulmonary artery.

De-oxygenated blood from the superior vena cava and inferior vena cava is routed directly to the lungs. Oxygenated blood is sent to the body through the anastomosed aorta and pulmonary trunk.

patient's aorta. The right ventricle then becomes a common ventricle, pumping blood through the aorta to the rest of the body.

Blood flow to the lungs is provided by means of a modified Blalock-Taussig shunt joining the innominate artery to the pulmonary artery. This increases the flow of oxygen-enriched blood that will be sent to the body. The Norwood operation also involves making a hole in the wall between the left and right atria. In medical terms this is known as an atrial septectomy.

After the Norwood operation, children require medical management with various drugs. Some drugs, such as digoxin, are needed to improve the strength of the heart's contractions, and other drugs, such as diuretics, are required to remove excess fluid from the body.

The second stage of reconstruction is undertaken between three and ten months of age. Stage two involves performing a bidirectional Glenn shunt or a hemi-Fontan. (This is also known as a partial Fontan or a Bidirectional Cavo-Pulmonary Shunt.)

A bidirectional Glenn shunt is performed by connecting the superior vena cava (SVC) to the right branch of the pulmonary artery. As a result, venous blood from the head and upper limbs will pass directly to the lungs, bypassing the right ventricle. However, the venous blood from the lower half of the body will continue to return to the heart.

While avoiding the risk of failure of a complete Fontan operation, the partial Fontan helps to relieve symptoms. The procedure decreases the volume of blood delivered to the single ventricle, thus reducing the amount of work that the ventricle must perform. Post-operatively, oxygen saturation is improved.

In addition, because the bi-directional Glenn is a low-pressure shunt, it does not carry the risk of causing thickening and hardening of the blood vessels of the lungs. (This is a normal response of the lung's blood vessels to high pressures.) This operation creates a more favorable setting in which to complete a Fontan reconstruction at one and a half to two years of age.

At 18 to 24 months of age, if the patient does well after the Glenn shunt and pulmonary resistance remains low, the third stage of reconstruction is possible. This involves the completion of the Fontan procedure (as described in the earlier discussion of tricuspid atresia).

With the Fontan operation, the venous blood from the lower part of the body is also diverted to the lungs, thus creating the 'complete' Fontan circulation. However, if the child is not well or the pulmonary resistance is considered too high, then no further surgical treatment is possible.

Transplantation

Heart transplantation is carried out using the same basic techniques as for other transplants. In the case of pediatric heart transplants, the greatest problem is that infant donor hearts are in short supply. Thus transplantation is a treatment for only a limited number of babies with hypoplastic left heart syndrome. In addition, recipients can survive only with the assistance of heavy doses of expensive medication to prevent rejection of the transplanted tissue. These drugs also have significant side-effects, such as the risk of infection and lymphatic cancer, and must be taken by recipients for the rest of their lives. For those reasons, heart transplants are not considered the standard treatment for children suffering from HLHS.

SUMMARY

The defects mentioned in this chapter are not an exhaustive list of each and every defect or lesion that pediatric cardiac surgical programs are called upon to deal with. There are other defects not listed here that would be seen by professionals involved in the care of children with heart problems.

Nor is this chapter to be taken as being an authoritative statement of what the defects involve and how best they are treated. For such information, readers should refer to authoritative medical literature and texts. In addition, it is also important to note that frequently there are individual variations in each of these lesions. No two cases are alike.

This chapter is intended only to acquaint the reader with those defects that will receive the most attention in this Inquiry. As one reads through the following chapters, reference back to the information contained in this chapter (as well as in the Glossary and in Chapter 3) may be helpful.

RISK AND PEDIATRIC CARDIAC SURGERY

There is always risk involved in pediatric cardiac surgery. Various attempts have been made to estimate the level of risk associated with surgically treating each of the known pediatric congenital heart lesions.

During the course of 1994, parents in Winnipeg were given estimates by the doctors involved as to how many patients were likely to survive a particular procedure. At the time, there was no single book or list of percentages that contained a definitive estimation of the risk for each procedure, although information was available from pediatric cardiac surgeons and cardiologists working in other centres. Risk depends on many factors, including the specifics of the patient's condition, the skills and experience of the team, available technology and the overall growth of medical knowledge. One variable that recent research has focused attention on is the relationship between the numbers of cases a hospital deals with and results as measured by mortality.

Two academic articles presented to this Inquest examined this question. The articles were "In-Hospital Mortality for Surgical Repair of Congenital Heart Defects: Preliminary Observations of Variation by Hospital Caseload," by Kathy J. Jenkins MD MPH, Jane W. Newburger MD MPH, James E. Lock MD, Roger B. Davis ScD, Gerald A. Coffman MSc and Lisa I. Iezzoni MD MSc, published in the journal *Pediatrics* (Volume 95, Number 3 (March 1995), pages 323–330) and "Pediatric Cardiac Surgery: The Effect of Hospital and Surgeon Volume on In-Hospital Mortality," by Edward L. Hannan PhD, Michael Racz MS, Rae-Ellen Kavey MD, Jan M. Quaegebeur MD PhD and Roberta Williams MD, published in the journal *Pediatrics* (Volume 101, Number 6 (June 1998), pages 963–969).

Both articles came to similar conclusions. The Jenkins study made the following comment:

> In our study population, the risk of dying in-hospital was much less for children who underwent surgical correction of a congenital heart defect at institutions with the highest volume of such patients, in comparison with lower volume centres. Outcomes at the highest volume institutions appeared clearly different than those for other institutions; below 300 cases annually, no consistent trends in mortality by annual case volume were observed. (Jenkins et al, pages 327–328)

The Hannan study commented:

> Findings of the study were that annual hospital volume and annual surgeon volume were both significantly related to inpatient mortality rates, even after controlling for patient age and several clinical risk factors in addition to procedure complexity. The maximal differentiation in mortality rates between high and low-volume providers was 100 procedures annually for hospital and 75 procedures annually for surgeons. (Hannan et al, page 968)

This issue of the relationship between the number of procedures carried out in a pediatric cardiac surgery program and the mortality rate is one that will be returned to later in this report.

Chapter 3

THE DIAGNOSIS OF PEDIATRIC HEART DEFECTS AND THEIR SURGICAL TREATMENT

SPECIAL ISSUES IN PEDIATRIC MEDICINE

Pediatrics involves the treatment of children and has long been recognized as a separate medical specialty because of the differences in the medical issues that children and adults face. The care and treatment of children, in fact, can involve medical conditions that simply are not seen in adults. Some conditions are so unique to children that, if treated successfully in childhood, they will never manifest themselves again.

GENERAL ISSUES

The first major difference between adult and pediatric patients arises from the disparity in their sizes. While this disparity becomes less of an issue with older and teenaged children, where younger children and neonates (at the HSC, those less than six weeks of age) are concerned, the size of bodies and organs is a significant factor. The common statement that 'your heart is approximately the size of your fist' takes on enormous significance when one considers the size of a newborn's fist. The size of a baby's heart, in fact, has been compared to the size of a peach pit.

A second major difference is that a child is less able (and sometimes less likely) than an adult to articulate his or her medical problems and concerns to a doctor. Infants, and other children who are unable to speak, present a particularly difficult issue. While a doctor can be guided by a description of symptoms from an adult in assessing a particular medical problem and in determining the best course of treatment, that guidance remains elusive where children are concerned. Thus the determination of a child's health problems relies more heavily on observation and examination than is the case with adults. Of necessity, great reliance is placed on second-hand information about issues, such as how the child is eating or behaving. This information is usually gathered from people who are not medically trained (such as those adults involved in the care of the child).

It is true that adult patients are sometimes unable to articulate their problems (because of physical or intellectual limitations and even for psychological reasons), but this is invariably the case with infants. Thus the person diagnosing the child's medical problems must not only exercise care and attention to detail, but also must pay great attention to what might be considered extraneous information.

These factors also place the parent or guardian of the child in a position of considerable dependency (and therefore of trust) on the medical practitioner or nurse, when it comes to assessing the child's condition and recommending a particular course of action.

Besides size and lack of ability to speak, infants present other differences too. These include anatomical (the structure of the body), physiological (how the body works) and pharmacological (how the body responds to drugs) differences.

AN ISSUE SPECIFIC TO CARDIAC CASES

A major difference between adults and children arises in the area of cardiology and cardiac surgery. Children with cardiac problems tend to have congenital heart defects while adults tend not to have such defects. Additionally, no two children with the same type of cardiac lesion will present in exactly the same way, whereas adults with heart problems tend to have similar presentations. The anatomy of each congenital heart defect can differ significantly from one to the next, whereas adult hearts tend to appear the same, with medical problems that do not show anatomical differences.

The process of assessment and treatment of pediatric patients attempts to determine the anatomic anomalies unique to each child. Doctors treating children with heart problems have come to expect that, while in every case a child's cardiac defect can be categorized, what may be seen when a surgeon opens the child's chest can differ substantially from child to child. This may be so even when the children have the same category of defect.

PEDIATRIC SUBSPECIALTIES

All medical practitioners undergo training initially at medical school to become medical doctors. They then undergo a period of training in one or more teaching hospitals as a 'resident', during which they are assigned to work on various wards of the hospital. After that period of residency they can apply for a licence as a general medical practitioner or can continue training in a specific area of specialty, such as pediatrics.

Being licensed as a doctor and being recognized as a specialist are separate issues altogether. While training is generally the field of the academic community (universities and teaching hospitals), licensing is left to the various licensing authorities in each province. Recognition as a specialist in this country is the purview of the Royal College of Physicians and Surgeons of Canada.

As the specialty of pediatrics has expanded, so have the number and types of subspecialties, or more specialized areas of medical work. These include pediatric cardiology, pediatric cardiac surgery and pediatric anaesthesia.

PEDIATRIC CARDIOLOGY

Cardiology is the science of evaluating the condition of a patient's heart, identifying problems associated with it and recommending treatment for the conditions identified.

The cardiologist's most important function is the identification and diagnosis of heart defects and heart disease. These doctors stand at the front line in society's fight against heart problems, for it is their ability to identify a patient's heart condition quickly that will give rise to early intervention and successful treatment. While some heart conditions can be successfully treated without surgical intervention, it is the cardiologist who is usually the first to identify a condition that may require a heart operation. Invariably, the decision to proceed with cardiac surgery is a decision made between the patient, the family, the cardiologist and the cardiac surgeon.

If it is thought that surgery may be required, the cardiologist is expected to be able to provide a clear picture to the surgeon as to the exact state of affairs within the heart itself. For example, the functioning of valves and the location of defects, such as a hole in the wall separating the chambers of the heart, must be accurately described. This permits the surgeon to determine if surgery is, in fact, the best option and what the potential surgical issues are likely to be.

Often, in order to make a diagnosis, the pediatric cardiologist must do more than merely observe external signs, since these can sometimes indicate only that there is a problem and not what the problem is. More direct exploratory methods may have to be undertaken. Since children are usually unable to explain or describe their condition, a pediatric cardiologist's diagnostic skills emphasize the use of technology and accurate measuring devices to allow the cardiologist to form opinions and conclusions as to the cause of a child's apparent heart problem. Cardiologists now perform their tasks with the aid of modern technology unavailable to their colleagues of previous eras.

Some of the technologies available to today's cardiologist are:

- electrocardiography (the production of electrocardiograms or ECGs/EKGs, which are graphs showing the electrical impulses produced by the heart);
- echocardiography (the production of echocardiograms or ECHOs) through ultra-sound imaging; and
- cardiac catheterization, which involves inserting a long, fine tube into the femoral artery in the groin, through connecting arteries and then up and into the heart. The tubing is connected to a device that allows the cardiologist to measure the various pressures within the heart and the blood vessels surrounding it. The cardiologist may also take samples of blood for testing or inject special X-ray contrast material or dye through the tubing to obtain real-time pictures of how the heart works.

Intra-operative echocardiograms can be done in more than one way. One technique uses an external probe placed on the chest. However, it cannot be used throughout the entire operation. The other technique uses a transesophageal echocardiography probe (referred to as TEE) inserted into the esophagus. TEE provides superior images of structures in the heart without interference from the chest wall. For example, by imaging from directly behind the left atrium, TEE can produce minute detail of the mitral valve and the atrial septum. Since the probe is in the esophagus, it can produce ECHO images throughout the operation without interrupting the surgical procedure. Usually the probe is inserted by the anaesthetist and manipulated by either the anaesthetist or a cardiologist. Many cardiac anaesthetists now possess the skills to interpret the TEE.

While the HSC gained access to TEE equipment during 1994, none of the anaesthetists or cardiologists had experience with TEE.

In addition, a new field of invasive cardiology has developed in recent years. Cardiologists who have specialized in this field use technology to carry out procedures within the heart without having to cut open the patient's chest. For example, an 'invasive cardiologist' might perform a balloon atrial septostomy (as described in Chapter Two).

PEDIATRIC CARDIAC SURGERY

Surgery is a course of treatment that involves operating on the body of the patient, and cardiac surgery involves surgery on, within and around the heart. Cardiac procedures can involve operating on blood vessels attached to the heart or on the surface of the heart, or can involve operating on the heart itself, where the walls of the heart are actually opened up. Cardiac surgical procedures are referred to as either closed or open-heart surgery.

Closed-heart surgery is that surgery in and around the heart which does not involve having to either bypass blood from the heart or stop the flow of blood to the heart. Open-heart surgery is that surgery which often, but not always, involves actually opening the walls of the heart. Open procedures are those that require that blood-flow through the heart be diverted though the heart-lung machine, because the heart itself or its major blood vessels must be opened.

Adult cardiac surgery is an area of specialty that has enjoyed wide acceptance and recognition as a medical specialty for many decades. By contrast, pediatric cardiac surgery is a relatively new area of specialization. Indeed, it has only been since the latter part of the 1950s that science and medicine have begun to address the special issues that infants and young children with cardiac anomalies presented.

Initially, persons trained as adult cardiac surgeons performed cardiac surgery on children. However, the training that an adult cardiac surgeon receives is now considered insufficient for the complex procedures performed in pediatric cardiac surgery. Specialty training programs for pediatric cardiac surgeons are now found at a number of hospitals in North America, including McGill University in Montreal, the Toronto Hospital for Sick Children and Harvard Medical School in Boston.

If a doctor wishes to specialize as a surgeon, a further period of residency in a surgical training program is required, with additional periods of training in other specific fields. For a pediatric cardiac surgeon, that would involve training initially as a general surgeon, then as a cardiothoracic surgeon, then as a cardiac surgeon, then as a pediatric cardiac surgeon. Training in this specialty can exceed ten years.

ANAESTHETISTS

Anaesthesia is the field of medicine involving the administration of drugs that produce a loss of consciousness or sensation. Most often, anaesthetics are given for a surgical procedure but sometimes, especially in the case of children, anaesthesia may also be needed for a diagnostic procedure, such as a special X-ray examination.

Anaesthetists are doctors who have completed their medical degree and have then completed an additional residency in the study of anaesthesia and anaesthetics. This residency usually lasts a minimum of five years. In Canada, the term 'anesthesiologist' is gaining wider acceptance as the term applied to such doctors. However, as the witnesses in this Inquest used the term 'anaesthetist,' that term will be used throughout this report.

Anaesthetists have extensive knowledge of the drugs used to enable patients to undergo surgery without pain and suffering. Anaesthetists are also very knowledgeable about how the body works and the various techniques and treatments needed to maintain patients in a state whereby the necessary surgical procedures can be carried out in a safe manner. Another of the anaesthetist's responsibilities is to determine if a patient is in a condition to be safely anaesthetized and undergo an operation.

While pediatric cardiac surgery and pediatric cardiology are viewed as distinct specialties with a distinct training regimen, such is not the case with pediatric cardiac anaesthesia. There is, in fact, no separate training program for pediatric cardiac anaesthetists recognized by the Royal College of Physicians and Surgeons of Canada. Anaesthetists who specialize in pediatric cardiac anaesthesia generally have been trained in adult cardiac anaesthesia. Some may have undertaken an additional six to twelve months of training in a fellowship program in pediatric cardiac anaesthesia. Others will have developed their expertise in pediatric cardiac cases through experience, as opposed to any special training regimen. In addition, pediatric cardiac anaesthetists in Canada have developed their own ongoing medical education programs to improve their knowledge and skills.

NURSING

Nurses care for the sick and disabled, and promote, restore and maintain health. These services are usually co-ordinated with doctors and other health-care providers. By virtue of their education, experience and 24 hour-a-day presence with patients, registered nurses (RNs) play a unique and critical role in hospital care. Some of this care is in specialized areas, such as the operating room and intensive care unit, and nurses working in these areas are expected to develop the knowledge, skills and judgment essential for the management of complex patient problems. RNs are often the first to identify changes in a patient's condition, as well as trends in a patient's response to care. Nurses often act as a guide and interpreter for patients and their families trying to negotiate the complex and highly specialized environment of hospitals. RNs also provide the co-ordination of care and day-to-day management for both individual patients and patient care programs, ensuring that the right resources are in the right place at the right time to meet patient needs.

Scholars of the history of nursing in Canada stress the need to examine the role that gender stereotyping and discrimination has played in the history of nursing. Women dominate the profession of nursing. Approximately 98 per cent of nurses in Canada are female. Furthermore nurses, like most women who entered the Canadian labour market, were historically poorly paid and were expected to be completely obedient to male authority. In fact, the motto of Canada's first successful school of nursing, the General and Marine Hospital established in 1874 in St. Catharines, Ontario, was "I see and am silent." (Judy Coburn, "I See and Am Silent," in *Women and Work*, 1850–1930, Toronto: Women's Press, 1974, page 140)

For most of this century, Canadian nurses received their training in hospitals, where they served essentially as free labour to the hospitals as they apprenticed to their craft. Students were often required to live at their training hospital, where they regularly worked 12-hour days, 7 days a week. According to Katheryn MacPherson, author of a recent history of nursing in Canada:

> Deferring to one's superiors was learned early on the job. Probationers entered the hospital at the bottom of the nursing hierarchy, subordinate to juniors, who in turn looked up to intermediates, who deferred to senior students. Seniors were expected to comply with the directives of supervisory graduate nurses, who themselves answered to the superintendent of nursing. Deference extended well beyond merely following orders to include physical demonstrations of differential rank. Nurses were instructed that, when in the presence of more senior nursing staff or any medical practitioners, they were to stand up 'at attention', surrender their place on elevators, and allow superiors to walk ahead. (Katheryn MacPherson, *Bedside Matters: The Transformation of Canadian Nursing, 1900–1990*, Don Mills, Oxford University Press, 1996, page 32)

While it has been possible to receive a Bachelor of Science in Nursing (B.Sc.N.) in Canada since 1919, the number of university training programs and the number of university-trained nurses in Canada remained low for most of the century.

Historically, nurses trained in hospitals for three years. During this period they constituted the main nursing labour force, while most graduate nurses provided supervision, not bedside care. When they graduated, nurses sought work in private care, public health or hospitals. While today approximately three out of every four nurses work in a hospital, for the first half of this century a very large percentage of nurses sought and found work in private practice. Graduating nurses took examinations that permitted them to be registered with local nursing registries, hence the designation Registered Nurse. These registries served as referral services and provided a variety of services to the nurses who were registered with them, including sick benefits and pension funds.

The focus of the diploma programs was to prepare nurses to provide care in hospitals and personal care homes, with the curricula focused on the nursing response to people suffering illness and disease. The baccalaureate curriculum still provides this focus, as well as requiring a broader foundation in the arts and sciences. Courses include anatomy, physiology, psychology, sociology, and both theory and clinical practice in nursing. In addition, there is an expectation that students learn scientific reasoning and how to apply current research to practice. The degree provides students with an in-depth knowledge of the determinants of health, which enables graduates to be effective in helping individuals, groups and populations prevent illness and lead healthier lives, as well as provide nursing care for those who are ill.

The last twenty years have also seen a dramatic expansion in nursing specialization—close to one-third of nurses are enrolled in post-RN training. Despite this expansion in training, formal recognition for specialized training has been slow in coming.

More recently, governments have closed hospitals and beds. Hospitals have moved toward reducing the length of time that patients spend in hospital, whether it be after having an operation, a baby or heart attack.

This has resulted in an increase in the percentage of very ill patients in hospital, and markedly influenced the workload of the nurses who care for these patients.

During the last decade, hospitals across Canada have experienced difficulties attracting and retaining nurses. This is the result of several factors. Within Canada's health-care system, nurses occupy a unique and yet controversial position. Nurses have many of the responsibilities and obligations of professionals, and indeed, they are trained as professionals. However, they lack the control over working conditions that usually accompanies professional status. This, in combination with the increase in the workload and what is perceived as low pay for the care that nurses provide, has caused many to leave the profession. In addition, hospitals involved in cost-cutting efforts have looked for ways to reduce further their nursing costs—making greater use of part-time staff and having more tasks performed by non-nurses. Unintentionally, this has sent the message to current and potential nurses that the profession has a cloudy future. The Winnipeg HSC was participating in such an exercise in rationalization in 1993 and 1994.

The events in the pediatric cardiac surgery program in 1994 involved nurses who specialized in the nursing diagnosis and therapy of patients with cardiac problems, in cardiac surgery and in the intensive care treatment of young children in critical condition. All the nurses involved had a variety of educational backgrounds and different personal responses to the events of 1994. Those responses were shaped by their profession, its history and the place that it occupied in the broader health-care system.

HOW A PEDIATRIC CARDIAC SURGERY CASE PROCEEDED

The rest of this chapter sketches out in a general fashion the manner in which pediatric cardiac surgery was undertaken in Manitoba in 1994. Just as each patient is unique, each case was also unique, with the actual sequence of care differing in some respects from the procedure described below.

EVENTS LEADING UP TO THE DAY OF SURGERY

Diagnosis

A cardiac case began with the diagnosis. A child's heart problem might be noted at any point before or after the child was born, by the mother's doctor during a prenatal examination, by the doctor attending at the birth, by the child's pediatrician or by the family doctor during a routine checkup.

Once a heart problem was discovered, in Manitoba during 1994, the child was usually referred to the Variety Children's Heart Centre at the Winnipeg Health Sciences Centre to be seen by a pediatric cardiologist.

Variety Children's Heart Centre clinics

A child who was referred to the Variety Children's Heart Centre (VCHC) by a pediatrician or family doctor would be seen at one of the centre's regular clinics. These clinics were conducted by the cardiologist, the nurse clinicians and the technicians who were assigned to the VCHC. The necessary diagnostic tests would be performed at the clinic, and parents would normally be provided with test results before they left. The nurse clinicians would both assist with the tests and provide support to the families once the test results were provided. The nurse clinicians usually reinforced the information the parents had heard from the cardiologist. If a complex problem was detected, a cardiac catheterization might then be required. Catheterization procedures are usually performed to examine, in intricate detail, the anatomy and circulation of a patient's heart. Such information is essential in advance of surgery (and other treatment).

Surgical consultation

If the cardiologist believed the patient required surgery, he would consult with the pediatric cardiac surgeon. The surgeon would usually examine the patient and determine if the heart defect required surgical intervention. The surgeon's obligation was to assess the information available about the child and determine if, in his opinion, the child's problem could be best addressed surgically and where the operation could best be done. The surgeon could refer the patient to another heart centre, if he thought that the problem was beyond the team's ability or if the specific operation could best be done elsewhere.

The surgeon was expected to consider the particular lesion, the child's condition, his own skills and the skills of the operating team, and any special needs that the operation might require in terms of equipment, environment and organization. The surgeon would advise the cardiologist of the outcome of his meeting with the parents. He would also be expected to discuss his conclusions with the parents.

The nurse clinician would attend the meeting between the surgeon and parents. Part of the nurse clinician's role was to reinforce the information the surgeon told the parents. The nurse clinician also acted as ongoing support for the parents throughout the hospitalization and would continue the relationship during follow-up at the VCHC clinic.

Cardiovascular thoracic conferences

In all cases where surgery was indicated or considered possible, the matter was referred to a weekly meeting usually held every Wednesday morning at 0700 hours and known as the Cardiovascular Thoracic Conference, or CVT conference. At the CVT conference, the cardiologist, the Variety Children's Heart Centre nurses and the surgeon discussed the case. If any interns or residents were working on the cardiology service, they too would be present. Technicians who conducted the diagnostic tests at the VCHC with the cardiologists might also attend, if their reports were being considered. The purpose of the discussion was to decide if and how to proceed with the case and consider other issues, such as whether or not the case should be scheduled (or slated) for surgery in Winnipeg. Other hospital staff, such as operating room nurses, anaesthetists and intensive care staff were not usually included in the CVT conference.

The surgeon or the cardiologist advised the referring doctor of the diagnostic findings and the decisions made in the CVT conference by letter and/or charted the information in the Patient Progress Notes portion of the hospital record (in the case of emergency operations).

Consent

Before the operation took place, the child's legal guardians needed to give their consent in writing. This would occur after a discussion that should have included a full explanation of the need for surgery and a full explanation of the risks, including complete answers to all questions asked. At the Health Sciences Centre, the responsibility to explain a surgical procedure and obtain the appropriate consent from the parents fell to the surgeon. The practice at the HSC was to have the consent form signed just before the day of surgery, although the meeting explaining the procedure might have taken place several weeks before.

Scheduling of the operation

A child scheduled for surgery might be considered as an emergency case, an urgent case or an elective case. The difference among these three descriptions would be determined by how soon the operation had to take place. Emergency cases needed to be operated on as quickly as possible, while urgent cases could endure a longer time delay. In emergency cases, often the CVT conference and the actual pre-operative assessment were combined to expedite surgery. Elective cases were planned for in advance, with a considerably longer time frame, even though they were ultimately necessary for the life of the child.

If a child was assessed with a heart defect shortly after birth, an operation might be scheduled while the newborn was still in hospital. If the operation could wait, the child would be discharged home, with follow-up in the VCHC. Infants with heart defects who were born in other hospitals would be transferred to the Children's Hospital or referred to the VCHC for assessment.

Admission to hospital

In elective cases, the family would receive a letter from the VCHC, stating the date the child was booked for surgery, when to come for admission to the hospital and other details. Along with the letter, the family would receive a pamphlet describing the surgical ward (CH3) that the child would be in and other general information.

The child would usually be admitted to the Children's Hospital at least one day before surgery. The VCHC would forward to the hospital the results of any tests done on the child on an outpatient basis as part of the pre-operative preparation. There was also a patient education record that was filled out by different nurses, starting with the VCHC nurse clinician. This record documented the steps taken to educate the parents and patient (where appropriate) about the particular heart problems and prepare the child for surgery. The nurses would explain the hospital experience to the family. They would discuss such matters as pain control and the fact that the patient would be looked after by a number of different people doing different tasks. One of the important responsibilities of the VCHC nurse was to ensure that parents understood that they could ask any questions and that they did not have to sign a consent for surgery until they felt prepared to do so.

Pre-operative conference

The pre-operative conference for each case was held on Tuesday mornings in the week before the date of surgery. The cardiologist, the surgeon, the VCHC nurse clinicians, operating room nurses, anaesthetists, intensive care doctors and nurses, perfusionists and respiratory therapists attended this meeting. Since the HSC was a teaching hospital, interns, residents, and fellows might also be present.

While the intent was that the staff who were going to be involved in the operative procedure or follow-up care of the patient attended this meeting, often, due to other commitments, someone else would attend in their place. However, it was expected that if this happened, the person attending the meeting would brief the person actually participating in the case.

The meeting involved a presentation of the cases scheduled for surgery the following week, with the diagnostic part of the presentation being made by the cardiologist and the surgeon providing information and answering questions about the operation. Any of the people in attendance asked whatever questions they needed to ask. The child's complete medical history and current status, as well as the results of medical tests, were outlined. Echocardiograms and videotapes of the cardiac catheterization that illustrated the patient's condition might be shown. The VCHC nursing staff would also present information on the child's social circumstances.

Pre-operative anaesthetic evaluation

Following the pre-operative conference, the anaesthetist would examine the patient and the patient's chart. In this examination, the anaesthetist would confirm the information provided at the conference and would examine the patient to discover if there were issues specific to the anaesthetic, such as whether or not the patient had a normal airway. Since the material presented at the conference could be several days old by that time, the anaesthetist would check to see if the child's condition had changed or if there were more up-to-date test results. If chest X-rays were not available at the pre-operative conference, the anaesthetist would attempt to view the X-rays and/or the X-ray reports.

The parents were often present during this evaluation, giving the anaesthetist an opportunity to discuss the child's medical history, the family's medical history and family issues relating to anaesthetics. The anaesthetist would explain the risks and problems of anaesthesia, what the anaesthetist would do and the drugs that might be used. At this point parents gave verbal consent. (In Canada there is generally not a separate written consent for anaesthesia, the need for an anaesthetic being covered by surgical consent.)

Following this meeting, the anaesthetist recorded any concerns and requested any additional necessary tests. An order would be placed with the pharmacy for any drugs that the anaesthetist needed to have made up ahead of time. The anaesthetist might also approach other specialists who might be dealing with the child to discuss issues that were not in the area of anaesthetic expertise.

The anaesthetist would also assign a status evaluation to the patient, which was based on the physical health of the patient. This evaluation used a classification system adopted by the American Society of Anesthesiologists (ASA), called the ASA Class. There are five classes, and adding the postscript 'E' indicates that the patient is to undergo an emergency operation. The classes range from ASA I, representing a very healthy patient, to ASA V, representing a patient who is not expected to survive 24 hours with or without surgery.

Most of the children who were the subject of this Inquest were assigned a Class III or IV. A Class III patient is one who has health problems that limit the ability to function normally. A Class IV patient has health problems that represent a constant threat to life.

Contact with the child and the family

Depending on the heart condition, the child might be living at home before surgery or might be in the hospital. Contact between the child and the child's parents and the hospital was maintained by the nurse clinicians working for the VCHC. It was their responsibility to prepare the family for both the operation and the post-operative period. Children who were not in the hospital were usually brought into hospital the day before the operation.

The nurse clinicians would also maintain contact with any child who was already in the hospital. In most cases, neonates would have been in the neonatal intensive care unit from the time of their diagnosis until the operation. Such a patient usually needed an emergency operation because of the severity of the heart condition: the heart defect was so serious that it had to be dealt with quickly or the child would die.

Preparation of the patient

It was the joint responsibility of the cardiologist, surgeon, anaesthetist and intensivist (where applicable) to ensure that a child was in optimum condition for surgery. Any one of these doctors might raise objections to proceeding with surgery if he or she thought that the child was not in optimal condition.

THE DAY OF SURGERY

Preparation of the operating theatre

Open-heart operations took place in Theatre 2, the largest of the Children's Hospital operating rooms, because of the need to have the cardiopulmonary bypass (CPB) machine in the room. If the operation was a closed procedure, Theatre 1 would often be used.

Theatre 2 was renovated before 1993, specifically to accommodate the special needs of pediatric cardiac surgery. The theatre was enlarged to contain the anaesthetic and perfusion equipment. Special wiring prevented power surges from affecting the heart-lung machine. At the same time, a new ventilation system was installed.

The term Operating Room, or OR, is used to describe both the suite of operating rooms in a hospital and the actual room in which surgery takes place. This room contains an operating table, an anaesthetic machine, monitoring equipment, an anaesthetic drug cart, equipment tables, intravenous poles and sterile drapes.

Operating theatre personnel

Besides the surgeon, assistant surgeon and anaesthetist, the personnel in the operating room consisted of:

- scrub nurses
- circulating nurses
- anaesthetic nurse
- perfusionists
- residents (on occasion)
- cardiologist (on occasion).

Scrub nurses

Most people who have seen an operation are familiar with scrub nurses. They are the nurses seen standing, usually at the elbow of the surgeon, overlooking the operative site and handing equipment to the surgeon as needed. The term comes from the fact that the scrub nurse has 'scrubbed in'—that is, has washed hands and forearms carefully and donned sterilized clothing. To maintain the sterility of the operative field, a scrub nurse does not leave the side of the operating table until the procedure is completed or another nurse has scrubbed in.

Although an operation could be performed with only one scrub nurse, there were usually two scrub nurses for the operations involving the 12 children under discussion in 1994.

Circulating nurses

Circulating nurses 'circulate' around the operating room and between the operating room and the outside, seeing to any equipment and other needs of the operating team, including those that might require outside contact.

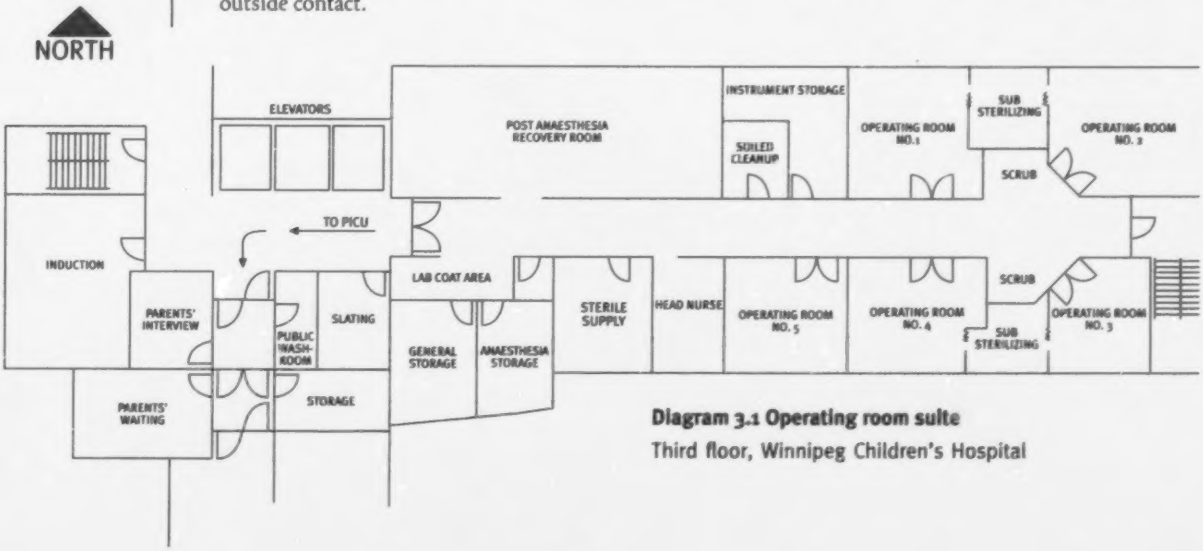
NORTH
ELEVATORS
POST ANAESTHESIA RECOVERY ROOM
INSTRUMENT STORAGE
SOILED CLEANUP
OPERATING ROOM NO. 1
SUB STERILIZING
OPERATING ROOM NO. 2
SCRUB
TO PICU
INDUCTION
LAB COAT AREA
PARENTS' INTERVIEW
PUBLIC WASH-ROOM
SLATING
GENERAL STORAGE
ANAESTHESIA STORAGE
STERILE SUPPLY
HEAD NURSE
OPERATING ROOM NO. 5
OPERATING ROOM NO. 4
SCRUB
SUB STERILIZING
OPERATING ROOM NO. 3
PARENTS' WAITING
STORAGE

Diagram 3.1 Operating room suite
Third floor, Winnipeg Children's Hospital

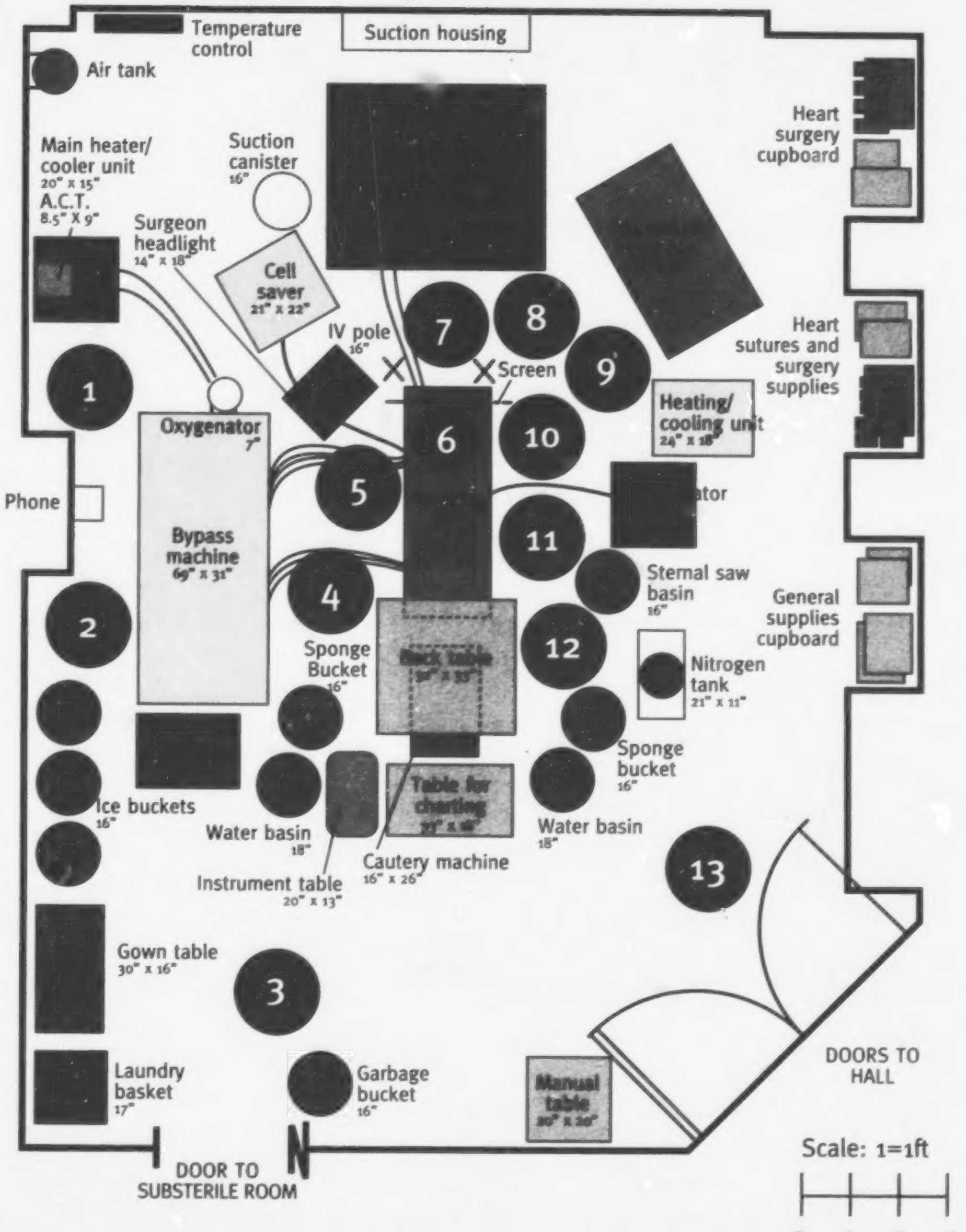
Temperature control
Suction housing
Air tank
Main heater/ cooler unit 20" x 15"
A.C.T. 8.5" X 9"
Suction canister 16"
Surgeon headlight 14" x 18"
Cell saver 21" x 22"
IV pole 16"
Screen
Heart surgery cupboard
Heart sutures and surgery supplies
Heating/ cooling unit 24" x 18"
ator
Oxygenator 7"
Bypass machine 69" x 31"
Phone
Sternal saw basin 16"
General supplies cupboard
Nitrogen tank 21" x 11"
Sponge Bucket 16"
Back table 30" x 33"
Sponge bucket 16"
Table for charting
Ice buckets 16"
Water basin 18"
Water basin 18"
Cautery machine 16" x 26"
Instrument table 20" x 13"
Gown table 30" x 16"
Laundry basket 17"
Garbage bucket 16"
Manual table 20" x 20"
DOORS TO HALL
DOOR TO SUBSTERILE ROOM
Scale: 1=1ft
0 1 2 3
1
2
3
4
5
6
7
8
9
10
11
12
13

Diagram 3.2 Operating room number 2

1	Primary perfusionist	6	Patient	11	Second surgical assistant
2	Secondary perfusionist	7	Anaesthetist	12	Second scrub nurse
3	Circulating nurse	8	Anaesthetic resident	13	Circulating nurse
4	First scrub nurse	9	High risk anaesthetic nurse		
5	Surgeon	10	First surgical assistant		

In the case of the Pediatric Cardiac Surgery Program, the circulating nurse was usually in the OR, often observing the progress of the operation and assisting the scrub nurse as needed. Sometimes a circulating nurse would scrub in, to relieve a scrub nurse during surgery.

Anaesthetic nurse

The anaesthetic nurse assisted the anaesthetists during high-risk operations. The nurse set up the lines, such as an arterial line or a central line, prepared the anaesthetic drugs, attached monitors to the patient and took samples of blood for the measurement of blood gases. Once the child was on bypass, the anaesthetic nurse might leave the OR until the patient was ready to come off bypass. On return to the OR, the nurse would co-ordinate bringing blood products into the room, preparing special drugs for administration and assisting with resuscitation as necessary. She would prepare the transfer sheet that accompanied the child from the OR to the Intensive Care Unit, identifying any problems or issues that arose during the course of surgery. She would then help prepare the patient for transfer, accompany the patient to the ICU, help set up the patient in ICU and give a report from the transfer sheet in order to make the transfer smoother.

Perfusionists

The perfusionists operated the cardiopulmonary bypass machine and administered cardioplegia (a treatment that stopped the heart during the actual operation). There were two perfusionists in each operation under discussion during this period.

Residents

Since the HSC was a teaching hospital, at times there would be residents or medical students, who would help either the surgeon or the anaesthetist. Surgical residents might be allowed to perform part of the procedure under the supervision of the surgeon, but most usually helped the surgeon by suctioning blood from the operative field or holding lines or instruments out of the surgeon's way to give him a clearer view. The resident was present primarily to learn. Anaesthetic residents might be permitted to administer drugs or insert tubes or lines, as directed and supervised by the anaesthetist. Usually, they also recorded (or charted) everything that occurred during the procedure.

Cardiologists

On occasion the surgeon would call for the cardiologist to enter the OR to help with identification of heart anatomy and discuss any issues with the case. The cardiologist would not scrub in but would wear OR garb and would then stand with the anaesthetist at the head of the OR table.

The team

These persons constituted the operating room team. Historically, the surgeon was seen as the captain of the surgical ship, particularly since the patient, in medical terms, belonged to the surgeon, although that view has changed over recent years. As a result, the lines of command in the operating room also changed.

The surgeon and the anaesthetist each were expected to have mastered separate medical specialties with distinct skills. Thus, neither the anaesthetist nor the surgeon was solely in charge. The surgeon was not responsible for matters relating to anaesthesia, while the anaesthetists were not responsible for the operation. They had a joint, if independent, responsibility for the patient's health and well-being. Both might discharge their duty by delegating certain aspects of the treatment to assistants who were properly qualified and experienced.

However, it would be a mistake to simply focus on these two doctors. An operating room team depends on the skills, dedication and talents of all of its members. A team is more than a collection of highly skilled individuals, charged with working together. While it is essential for each team member to have the skills needed to accomplish the task at hand, a team needs a leader who is skilled in problem-solving and decision-making. As a whole, the team must be able to communicate effectively and resolve conflicts. This requires effective interpersonal skills. In a strong OR team, leadership is shared, problems are solved through discussion, members are accountable to each other and performance is measured collectively and regularly.

Charts

A medical chart is a record of what was done to a patient in the hospital. It is the record of medical proceedings and is an important—and, in most cases the only—source of information available when a patient dies, for those who then attempt to assess what happened. The office of the Chief Medical Examiner for the Province of Manitoba must by law and by policy be called whenever a child dies during or after a surgical procedure. In determining whether or not to direct that an autopsy be ordered or that an Inquest be called, one of the first steps a medical investigator takes is to look at the medical chart for information about the patient's treatment. If the information on the chart is not accurate or lacks a material fact, the Chief Medical Examiner's office is unable to come to a proper conclusion.

The staff anaesthetist had the ultimate responsibility for charting on the anaesthetic record, but in some cases, a resident might do the charting. The anaesthetist charted the monitors used (such as types of lines), type of anaesthetic used, the drugs given, the dose and times they were given, the vital signs, the timing of bypass, intravenous fluids and blood products given and any problems that may have arisen.

The perfusionists entered their information on the Perfusion Record. They recorded pump times and rates, line pressures, blood chemistry and blood gas values, information on clotting time, the delivery of heparin, cardioplegia doses and any blood products given.

The circulating nurse was responsible for recording on the OR Count Sheet the OR times, the staff involved in surgery, the procedure performed and which specimens were sent for testing. A vital part of the record was the outcome of the needle, sponge and instrument count. To determine this, a count was made by the scrub nurse and the circulating nurse together.

The surgeon did not do any record keeping during surgery. However, at the end of the operation, the surgeon dictated an operative report. A copy was placed in the patient's hospital record.

There did not appear to be any systematic evaluation of surgical outcomes. Although the duration of each case and other factors were noted at the time, there was no process of tracking common indicators. These indicators could include duration of use of the heart-lung machine, duration of total circulatory arrest, volume of blood loss, number of units of blood transfused and number of blood components transfused: e.g., red blood cells, plasma and platelets.

The three phases of the operation

Every cardiac operation had three phases: pre-surgical, surgical and post-surgical. Sometimes these were quite distinct. At other times, because of the urgency of the operation and the condition of the patient, the first two phases might appear to occur almost simultaneously.

The pre-surgical phase

The pre-surgical phase started with the arrival of the anaesthetist. After suitable preparation, including attaching monitors, the patient would be anaesthetized, then positioned on the table for the operation. Special padding would be placed to protect the child. The area of the operation (also known as the 'surgical field') would be washed (or 'prepped') and then draped with sterile towels, ready for the first incision.

These procedures were undertaken in the operating room. The anaesthetist largely performed the first step, preparing and anaesthetizing the child. The scrub nurse, often assisted by the surgeon, would do the prepping and draping of the patient. While these steps took place roughly in the order described, certain portions of these steps might be undertaken simultaneously or were completed in stages throughout the process of the start of the anaesthetic.

Arrival of the anaesthetist

The anaesthetist arrived in the operating room at least 30 minutes before the patient was scheduled to arrive. In high-risk cases the anaesthetic nurse and a respiratory technologist would assist the anaesthetist. The technologist would check equipment, such as monitors, while the nurse, under the direction of the anaesthetist, helped prepare necessary drugs and intravenous (IV) lines.

The patient and parents

After the arrival of the anaesthetist, the parents and child were brought to the waiting room, which was outside the operating room. The patient might or might not have been given a sedative before going to the operating room. In the case of infants and small children, the parents would carry their child in their arms to the operating room door and deliver the child into the arms of the waiting OR nurse.

Anaesthetic monitoring

Monitoring was an essential part of anaesthesia for pediatric cardiac surgery. Before the induction of anaesthesia, the anaesthetist would usually set up monitoring equipment. This equipment included devices to monitor:

- the heart beat (using an electrocardiogram and also through a stethoscope placed on the child's chest);
- blood pressure (first with a blood pressure cuff and then with a small plastic catheter inserted into an artery of the wrist, the foot or the groin); and

- heart and breath sounds (through the stethoscope placed on the child's chest). This stethoscope, which was placed on the child's chest, was known as a precordial stethoscope. This would be replaced later in the operation by a stethoscope that was inserted into the child's esophagus.

Oxygen saturation was also monitored. Oxygen saturation is a term that describes how much oxygen is in the blood. A normal saturation is 97–100 per cent. When air enters the lungs, oxygen moves from the air, into the lung tissues, through the walls of the very small blood vessels (capillaries) and into the blood. Some of the oxygen stays in the liquid (or plasma) of the blood. Most of the oxygen enters the red blood cells, where it combines with a special chemical, known as hemoglobin. The amount of oxygen that actually binds with the hemoglobin is known as the oxygen content. The amount of oxygen that could bind with the hemoglobin is known as the oxygen capacity. The ratio between the content (actual) and the capacity (possible) is the oxygen saturation.

Oxygen saturation can be easily measured by using a special probe, called a pulse oximeter. The probe is simply clipped onto a finger (or toe or earlobe), just like clipping on a clothes peg. No needles are inserted into the patient. Instead, the probe uses a special light beam to measure the oxygen saturation. The pulse rate is also measured, as the device notes each time a pulse of blood is pumped into the finger (or toe), each time the heart beats.

Most pulse oximeters make a beeping noise every time a pulse is detected. This beeping will increase or decrease in rate with the pulse. The pitch (or musical tone) of the beep will also change as the saturation decreases.

Other monitors were:

- a temperature probe;
- a special 'muscle twitch' monitor to assess the effects of the anaesthetic drugs that temporarily weakened or relaxed the patient's muscles; and
- an end-tidal carbon dioxide monitor, which was a special sensor to detect the amount of carbon dioxide in the patient's breath.

In addition, extra monitoring would be provided by special lines inserted into other blood vessels, such as the jugular vein in the neck, in the form of a central line (see below).

Not all the monitors would be attached or inserted until after the start of the anaesthetic. Some children would be well enough that only a few monitors were needed for induction. Other children might be too agitated to have all monitors attached or inserted until they were either well sedated or actually anaesthetized. In addition, other monitors, such as the urinary catheter (usually referred to as a Foley catheter), generally were not inserted until after the child was anaesthetized. The circulating nurse would insert the catheter to measure and collect urine output.

The placement of lines

There were at least two intravenous lines (or catheters) inserted into veins in either the child's hands or feet. These were referred to as peripheral IV lines because they were inserted into veins in the patient's extremities (or periphery). If the patient was to undergo intravenous induction of anaesthesia, a line would be inserted (or placed) to allow the delivery of the anaesthetic drugs.

Depending on the nature of the case, other lines might be inserted for monitoring purposes. These could include an intra-arterial line for the continuous measurement of blood pressure and the taking of samples of arterial blood during the course of the operation. Common arterial catheter sites included the vessels of the wrist, the foot, the groin and, in newborns, the umbilical vein.

Another line might be used to measure central venous pressure. (Central venous pressure reflects the filling pressure on the right side of the heart and blood volume status). In addition, central venous lines were often inserted to allow the rapid administration of drugs, fluids or blood and permit the insertion of pulmonary artery or pacing catheters. Sites used for placement of central venous catheters included the internal or external jugular veins, the femoral vein (in the groin), a vein in the elbow and the umbilical artery. Central venous catheters might also be placed directly into the right atrium during cardiac surgery (and were often termed 'RA lines').

In most cases, these lines were inserted by putting a needle through the skin and then threading the catheter through the needle. However, the lines could also be inserted by performing a 'cut-down', a procedure in which the skin was cut open and the vein or artery exposed, to make it easier to insert the catheter.

The catheters were then connected to tubing that was connected to transducers to facilitate the reading of pressures. (A transducer is a small device that changes the mechanical energy from the monitored pressure to an electrical signal captured on the monitoring screen.) The anaesthetists generally used two transducers (one arterial and one venous). The surgeon might require three transducers: one for a right atrial line, one for a left atrial line (an LA line) and sometimes one for a pulmonary artery line (a PA line). Depending on the operation, these lines might be put in intra-operatively and/or post-operatively. (Intra-operative is the term that refers to events that occur during the operation.) As long as these lines were in place, the transducers were left attached and were used in the ICU.

Induction and intubation

The induction phase of anaesthesia was the process of rendering a patient unconscious by giving the patient intravenous drugs through an intravenous line or inhaled drugs through a mask attached to a tube from the anaesthetic machine. After the anaesthetic drugs had taken effect, the anaesthetist then inserted a special breathing tube down into the patient's windpipe (in medical terms, the trachea).

The anaesthetist would not start the anaesthetic until receiving confirmation that the surgeon was in the hospital. The process of induction and intubation could then take from twenty minutes to two hours, depending on the condition of the child and any difficulties encountered.

INDUCTION

The anaesthetist would have determined which drugs were to be used to anaesthetize the patient. Initially the anaesthetic would be administered either intravenously or as a gas that the child breathed in. (In medical terms, this special gas is known as an 'inhalational anaesthetic agent' because the drug is inhaled or breathed in.) Once the child had lost consciousness, the anaesthetic would be continued with both intravenous and inhaled drugs. These drugs included sedatives (such as midzolam), narcotics (such as fentanyl, sufentanil, alfentanil and morphine) and an inhalational agent (such as halothane or isoflurane).

In addition, the child might also breathe in some nitrous oxide (known to many people as 'laughing gas'). The state of anaesthesia was maintained with further intravenous drugs and inhaled gases.

For these cardiac operations, the patients were also given specific anaesthetic drugs to weaken or relax their muscles. This helped the anaesthetist to be able to place the breathing tube into the trachea and then allowed the surgeon to operate on the chest without tearing the normally tight muscles of the chest. These special drugs were known as muscle relaxants. They included pancuronium, vecuronium and atracurium.

INTUBATION

Intubation refers to the placing of one tube inside another. The intubation that was referred to in a pediatric cardiac case was called endotracheal intubation. In this process a tube was inserted into the patient's trachea or windpipe, through either the nose or the mouth. The tube guaranteed a passage or 'airway' through which the patient could be ventilated. The tube also helped to prevent unwanted substances from going into the patient's lungs. To make intubation easier, the child was given a muscle relaxant.

As a result, the child would not be able to breathe and therefore required artificial ventilation. (This ventilation delivered oxygen to the lungs and removed carbon dioxide, in the same way that normal breathing did, except that the breathing was done for the patient.) First, the anaesthetist would hold a rubber mask over the patient's face, making an airtight seal. Then the anaesthetist would squeeze a special rubber bag that was attached by a rubber tube or hose to the mask. When this bag was squeezed, oxygen would be pushed from the bag, through the tube and mask, into the patient's nose and mouth and down into the lungs. Once the muscle relaxant was fully effective, the anaesthetist would insert the breathing tube in through the patient's nose or mouth and down into the windpipe or trachea. (In medical terms, this procedure is known as 'performing tracheal intubation'.) Once this tube was positioned and secured (usually with some tape), the anaesthetist would use a machine called a ventilator to breathe for, or artificially ventilate, the patient's lungs. This ventilation was delivered through the breathing (or endotracheal) tube.

Positioning, padding, prepping and draping the patient

The positioning, padding, prepping and draping of a patient could take half an hour.

POSITIONING

Most operations were carried out with patients lying on their backs. Occasionally, some operations were performed with the patient lying on his or her side. This meant that the patient had to be carefully turned and positioned, after the start of the anaesthetic and the placement of all the lines and monitors.

PADDING

The patient's head and face and the lines would be padded for protection during surgery. Padding was not a sterile procedure and was done by the circulating nurse, anaesthetic nurse and anaesthetist.

In some cases, the anaesthetist would pack ice around the patient's head and neck to cool the brain. This was done to protect the brain when there was to be a complete stoppage of both the heart and the heart-lung machine.

PREPPING

For heart surgery, the site of the operation (or 'operative field'), which was the chest, was then washed with a special antiseptic solution. The surgeon, or his assistant or the scrub nurse, would do this.

DRAPING

Because draping was a sterile procedure, it was done by the surgeon (or his assistant) and the scrub nurses. They placed sterile cloths or drapes over all but the operative field. A small, flexible screen would separate the patient's head from the surgical field. This screen would be draped with a sterile cloth to denote the barrier between the sterile surgical field and the patient's head, to which the anaesthetist would usually have access. This sterile drape was hung or draped in a manner to maintain the sterility of the area where the operation would be carried out.

The surgical phase

The surgical phase would start with the first incision and proceed until the completion of the operation. Pediatric cardiac operations were either closed or open procedures.

Closed-heart surgery

Closed-heart surgery was that surgery in and around the heart that did not involve having to stop blood flow to the heart. It therefore did not involve having to bypass blood around the heart or involve having to stop the heart from beating. Generally, closed-heart procedures were less risky than open procedures because the process of bypassing the heart did not need to be undertaken. Nonetheless these procedures did involve their own risks and some were as risky as or riskier than some of the simple open-heart procedures.

Open-heart operations

Open-heart surgery required the use of a cardiopulmonary bypass (CPB) machine. The CPB machine was a pumping device that diverted blood away from the heart, and returned it to the body at a point beyond the heart. Because the heart itself is essentially a pump, when it was stopped or blood was diverted around it, the CPB machine had to take over the pumping function of the heart. The CPB machine also allowed the blood that was pumped to pick up oxygen and be cleansed of carbon dioxide. These two essential functions were made possible through a membrane oxygenator that allowed oxygen to move into the blood and allowed carbon dioxide to move out of the blood.

The use of CPB was an important development in cardiac surgery. It has allowed surgeons to operate on the heart and major blood vessels while the patient's systems were otherwise maintained. However, a patient could not be maintained on CPB indefinitely.

A lengthy bypass would affect many aspects of a patient's system. The lungs would become wetter and the small airways would collapse. The liver and kidneys could be damaged. The heart could accumulate water and become swollen (or in medical terms 'edematous'). As a result, the heart could become less and less compliant and the heart muscle itself could also be damaged, contracting poorly, because of difficulties with techniques intended to protect the heart. (In medical terms, these techniques were known as 'cardiac preservation'.) The patient's blood could also be damaged. Increased CPB times could also increase the risk of air in the cannula lines, creating an airlock in the patient's blood vessels.

Open procedures could also involve stopping the heart from beating for a while. This was referred to as total circulatory arrest (or TCA). While open procedures were considered the riskiest of the cardiac procedures, those requiring TCA placed the patient at greatest risk. When the beating of the heart was stopped, the CPB machine was also stopped and blood flow through the body was stopped. In a procedure known as deep or profound hypothermia arrest (DHA or PHA) the body was invariably cooled to as low a temperature as possible (usually around 16–20 degrees Celsius) and the head was packed in ice. Despite such measures, however, TCA was a time-limited procedure. Most medical experts agreed that a period of 30 minutes of TCA would not likely impair brain function and that 45–60 minutes was the safest maximum period of TCA allowed. Beyond that time, most experts agreed that the chances of brain damage or neurological impairment increased dramatically.

There were three stages to an open-heart pediatric cardiac operation. These were pre-bypass, on-bypass and post-bypass.

PRE-BYPASS

The pre-bypass stage started when the surgeon made the initial incision and then proceeded to open the patient's chest. Before doing this, the surgeon made it clear that he was ready to start and gained assurances that all other members of the team were ready. The patient's body might react to the initial incision in ways that could not always be predicted. The anaesthetist then needed to respond to these changes by increasing or decreasing the amount of anaesthetic or administering other drugs or fluids, depending on the patient's reaction. For this reason, it was essential that the rest of the team be alerted to and prepared for the surgeon's activities.

There were certain procedures the surgeon needed to perform before going on-bypass. These could be addressing palliative repairs that had been done previously, carrying out repairs that could be done without going on-bypass (thus shortening the length of the bypass) and finally inserting the cannulas into the heart (cannulation) and attaching them to tubing for connection to the CPB machine.

The major elements of the pre-bypass portion of the surgery were:

- repairs;
- heparinization;
- cannulation; and
- cardioplegia.

Repairs In either open or closed-heart surgery, it was at this point in the operation that the surgeon attempted to carry out some of the necessary repairs to the heart. (These repairs were briefly outlined in Chapter 2.) It should be again emphasized that these repairs were extremely difficult to execute, given that the surgeon was working on a very small, very variable structure that might be moving with every heartbeat and every breath if CPB was not being used.

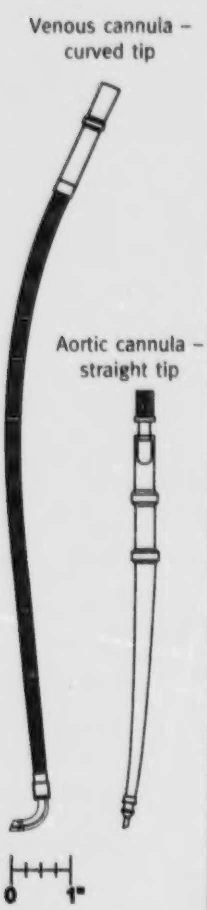

Diagram 3.3 Venous and aortic cannula

Heparinization In order to go on bypass, the patient's blood had to be treated with a drug called heparin to prevent it from clotting. If blood was passed through the heart-lung machine without heparinization, it would begin to clot immediately. This would be fatal to the patient. Before administering heparin, the perfusionists measured the child's activated clotting time (ACT). After the heparin was given, a second ACT measurement was taken to ensure that the patient was fully heparinized. After this, the clotting time was measured at regular intervals during bypass to ensure that it stayed above a set limit. The patient could then be cannulated, cardioplegia could be given and CPB could be established.

Cannulation The pediatric cannulas were tiny catheters used to connect the patient's heart to lines (or tubes) that were connected to the cardiopulmonary bypass machine (CPB). The cannulation procedure required the surgeon to insert the cannula into the major blood vessels (the inferior and superior vena cavas and the aorta) on either side of the heart. The cannula that was inserted into the aorta was referred to as the aortic cannula, while the cannulas inserted into the inferior and superior vena cavas were referred to as the venous cannulas. The venous cannula and the aortic cannula differed in shape to accommodate differences in the structure of the blood vessels into which they were inserted. It was important to carefully place the cannulas and the lines running to the CPB machine to ensure that they did not become dislodged. The aortic cannula, which connected the CPB machine via tubing to the aorta, was placed first, in case the patient needed to be transfused quickly. It was through this line that oxygen-rich blood was pumped. It was often the practice to place two cannulas in the vena cava, one in the SVC and one in the IVC. Oxygen-poor blood flowing from the body was then directed away from the heart, through these cannulas and to the CPB machine.

The actual process of inserting the cannula involved the following steps:

- inserting a suture thread around the portion of the blood vessel into which the cannula was to be inserted. This area was referred to as the cannulation site. Often in the case of aortic cannulation, two suture lines were placed around the cannulation site. Once this was completed, both ends of each suture line would extend away from the cannulation site. These lines were known as purse-string sutures.

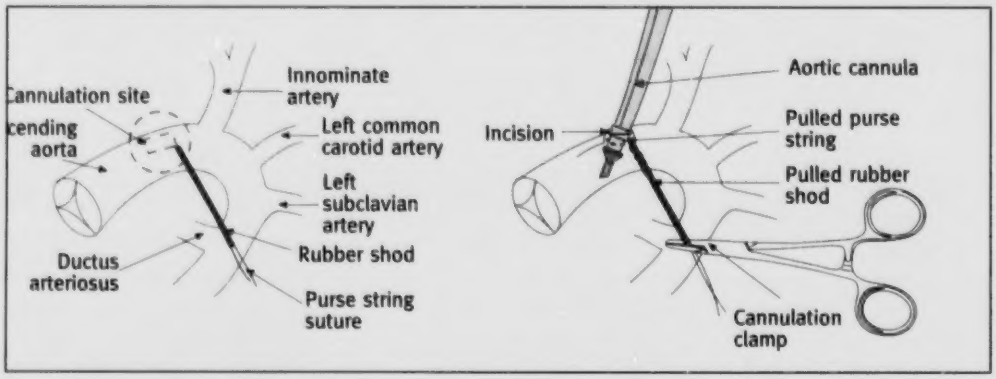

Diagram 3.4 Aortic cannulation

(left) Preparation of aortic cannulation site showing placement of single purse string sutures.
(right) Aortic cannulation site showing aortic cannula inserted and secured in the aorta.

- placing rubber sleeves, referred to as shods, over the suture line. These sleeves would facilitate the tightening of the suture lines at a later point in the cannulation.
- making an incision. At this point the surgeon would make an incision in the cannulation site with a scalpel.
- inserting the cannula. The tip of the cannula was then inserted through the incision into the blood vessel.
- tightening the purse-string sutures. The sutures were then tightened or snugged by pulling on them on the ends that extended through the shods. When they were tightened, they were held in place with clamps.

At this point the cannula would be connected to the line from the CPB machine.

Cardioplegia It was extremely difficult, if not impossible, to operate safely and quickly on a beating heart, particularly a tiny heart that might be beating at more than 100 times a minute. The heart therefore had to be stopped from beating. This was accomplished by the infusion of a high-potassium solution into the heart's coronary arteries, from a machine known as a blood cardioplegia device.

The stopped heart was deprived of oxygen and nutrient-rich blood and was at risk of damage. Injecting cooled oxygenated blood (that was mixed with the potassium solution) into the coronary arteries therefore provided the stopped heart with protection from this damage. The solution injected was known as a cardioplegic solution and provided what was known as myocardial protection. Because the cardioplegic mixture was extremely cold (approximately six degrees Celsius) it reduced the heart's metabolic state to the very lowest possible point once it had been arrested. Cardioplegia allowed the heart to maintain its energy stores and could also prevent the heart from beating for twenty to thirty minutes before an additional dose was required. During bypass, the EKG monitor would normally show a flat line. Any sign of electrical activity represented the need for further cardioplegia. It might be necessary to provide an additional dose of low potassium solution to maintain the arrest. To assist in this it was the perfusionist's role to remind the surgeon at intervals of approximately 20 minutes when the last cardioplegia had been provided. The surgeon decided, in consultation with the perfusionist, if another dose was to be given. The perfusionist would actually switch on the infusion, administer the solution and record the volume given.

ACIDOSIS

One of the conditions that often occur in children with congenital heart problems is acidosis. This is the accumulation of an abnormally high level of acidity, or low level of alkalinity, in the body fluids, including the blood. There are two general types of acidosis: metabolic acidosis and respiratory acidosis. Metabolic acidosis occurs when the body takes in too much acid, makes too much acid, or does not excrete enough acid through the kidneys. Respiratory acidosis occurs when the body retains carbon dioxide, which the body senses as an acid (carbonic).

Acid can come from increased production, usually of lactic acid, or when the body shifts into 'anaerobic' metabolism. This most often occurs when blood flow to the tissues decreases, and the tissues then shift from aerobic (with oxygen) metabolism to anaerobic (without oxygen) metabolism. When tissues are poorly perfused with blood, they do not use as much lactic acid as they normally do; this also contributes to an increase in the amount of lactic acid in the blood. In addition, severe acidosis may itself lead to reduced blood flow to the tissues, because the acid impairs the heart's ability to contract normally.

As the acidosis becomes worse, the patient starts to breathe faster and take deeper breaths, as the body tries to compensate for the excess acid. Finally, the heart weakens and the patient may progressively lose consciousness.

There are a number of approaches to treating acidosis. These involve increasing blood flow to the tissues by strengthening the heart, countering the acidosis by treating the child with bicarbonate and providing general supportive treatment in the form of oxygen and fluids.

ON-BYPASS

Following cannulation and the administration of cardioplegia, the bypass machine was connected to the patient through the cannulas and took over the heart's functions. This was the start of bypass and was known as 'going on pump'. After going on pump, the surgeon might need to operate inside the heart (referred to as intracardiac) and would therefore need to stop the heart.

The surgeon would take a special instrument, called an aortic cross-clamp, and use it to pinch or seal off the aorta. No blood from the heart could therefore go past the clamp and out to any part of the body, including the brain. The blood supply to the body and brain was then entirely from the CPB machine via the aortic cannula, with blood returning to the CPB machine via the venous cannulas, without passing through the heart's ventricles. The length of time that the cross-clamp was completely applied to the aorta would be recorded. This time would be known as 'cross-clamp time'. Another term was 'total ischemic time', which meant the time that the body was without blood flow and oxygen delivery during periods of circulatory arrest and profound hypothermia. (In medical terms, lack of blood flow is known as 'ischemia'.)

The heart would then be stopped and preserved with cardioplegic solution. The end of 'cross-clamp time' would be when the cross-clamp was partially or completely released. Even partial release of the clamp would allow some oxygen-containing blood to flow to the brain and other organs.

Blood Throughout the bypass portion of the procedure, blood would accumulate in the surgical field. The surgeon or his assistant would suction this blood away to allow the surgeon to see the operative site. This blood was filtered, added to the reservoir in the CPB machine and returned to the body. When required, additional blood could be transfused into the patient, through either the CPB pump or the IV lines. When necessary, bags of packed red blood cells were brought into the OR. These bags would usually be kept in a special refrigerator down the hall from the operating room. Before any blood was administered to the patient, it would be double-checked by members of the OR team to ensure that it matched the patient and the patient's blood type. Some blood products, such as fresh frozen plasma, would have to be thawed if they were required, while others, such as blood platelets, would have to be kept warm and agitated gently, to prevent them from congealing.

The HSC did not, as a matter of course, maintain a large supply of blood at the hospital. Blood products were kept by the Red Cross at its Winnipeg facility. Whenever a surgeon ordered blood products for an operation, the hospital had to request those products from the Red Cross ahead of time. The Red Cross, in turn, would approve the request and then arrange for delivery of the blood to the hospital in time for the procedure. If an emergency occurred and blood was needed quickly, the hospital did have a small supply of blood it could use. However, occasionally it was necessary to arrange for blood products to be delivered specially from the Red Cross—often by taxicab.

Throughout the operation the patient's blood would be tested (usually hourly) to check the hemoglobin concentration. The times when the blood was drawn and when the tests were conducted were usually noted on the chart.

Ventilation The anaesthetist was responsible for ensuring that a patient was properly ventilated during the operative procedure. Once the patient was on bypass, the anaesthetist would stop ventilating the patient, since the blood would receive its oxygen from the CPB machine. During these times, the ventilator would be turned off and the oxygen supply from the anaesthetic machine would be turned down, with just a small amount of oxygen being delivered down the endotracheal tube. With the ventilator turned off during surgery, the lungs would not balloon into the area around the heart and block the surgeon's view of the heart.

Before weaning The process of discontinuing bypass and allowing the heart to take over the pumping of blood throughout the patient's system was referred to as 'weaning from bypass'. In order for the patient to be weaned from bypass successfully, everyone involved in the operation–the surgeon, anaesthetist, perfusionists and nurses–had to work in a co-ordinated fashion.

Before weaning from bypass, the anaesthetist would suction the endotracheal tube, to remove any secretions that might have accumulated. In addition, a drug might be given to those patients whose airways might be sensitive to suctioning. (In medical terms they were said to have 'reactive airways'.)

Monitoring lines After an operation was completed, it was vital for the doctors and nurses caring for the child to be able to monitor the state of performance of the child's heart. To facilitate this, the surgeon would place monitoring lines in the child's heart before closing the chest. These monitoring lines were referred to as 'transthoracic lines' and were eventually connected to monitors in the ICU.

The surgeon would have to decide whether or not to place these monitoring lines before weaning the patient from bypass or if the lines could be placed after bypass was discontinued.

Usually the surgeon would insert the transthoracic lines in the atria and the pulmonary artery after decannulation (removing the cannula). These lines measured atrial and pulmonary artery pressures. The scrub nurse would hand the surgeon a sterile set of high-pressure lines. After inserting one end of the line into the heart chamber, the surgeon would hand the other end of the line to the anaesthetist, who would connect it to a transducer. The line with the transducer attached would then be available for the ICU staff to use when the patient arrived in the unit.

WEANING FROM BYPASS

Before the patient was weaned from bypass, the surgical team had to ensure that the patient was in optimal condition. Close attention had to be paid to the monitors and the condition of the repair. The anaesthetist had to ensure that the patient was well anaesthetized and relaxed. The anaesthetist also had to be ready to deal with any consequences that might arise from coming off bypass.

This included having special drugs ready to support the circulation. If there were concerns about the heart's ability to contract forcefully, inotropes (drugs that helped the heart to contract) might be given. If the patient's blood pressure was too low, the anaesthetist might administer a vasoconstricting drug, such as neosynephrine, to raise the pressure. If the blood pressure was too high, vasodilators (drugs that dilated blood vessels) would be used to dilate the vessels and thereby reduce the pressure that the heart was pumping against.

COMING OFF BYPASS

Patients were 'taken off' bypass in a gradual but sequential manner. The patient had to be rewarmed to normal temperature, the heart once more had to start beating, ventilation of the patient was restarted, the perfusion was brought to an end, pacing wires were inserted, the heparin was reversed and the heart cannulas were removed from the patient.

REWARMING

The rewarming period was begun by increasing the temperature of the blood being perfused through the arterial line to approximately 8–10 degrees Celsius above the venous blood temperature. Often vasodilators were given to produce a smooth and even rewarming process.

STARTING THE HEART

Before taking the patient off bypass, the surgeon needed to start the patient's heart beating again at a rate that was appropriate. In some cases, the heart would not beat fast enough. In other cases, the heart might need to be stimulated (with a small electrical shock) in order to start beating.

RESTARTING VENTILATION

Ventilation was usually restarted during rewarming, once the heart was closed.

STOPPING PERFUSION

When the cardiac action had reached a satisfactorily vigorous state, bypass would gradually be discontinued. Once the heart had taken over from the machine, the venous lines connecting the CPB to the heart were clamped.

INSERTION OF PACEMAKER WIRES

The surgeon would insert pacemaker wires at this point. The pacing wires were put in, even if the operation seemed to have gone well. Drugs might be administered to help increase the heart rate.

REVERSING THE HEPARIN

With the patient still heparinized, the team would then wait and monitor blood pressure and other vital signs. At this point an echocardiogram might be done to assess the repair. If all signs were appropriate, protamine would be administered to reverse the heparin. When the protamine was given, the anaesthetist needed to advise the perfusionists, because the perfusionists had to stop suctioning blood from the patient's chest cavity. If they did not, blood containing protamine might then be taken into the pump, with the risk of a blood clot in the pump.

DECANNULATION

When the surgeon was satisfied with the movement of blood through the heart, with the pressures in the chambers of the heart, and the blood pressure and heart rate (medically referred to as hemodynamics), the perfusion cannulas could then be removed. The cannulas were still in place when the protamine was given. However, with the administration of protamine, the chance of clots forming around the cannulas increased and the cannulas had to be removed.

The surgeon would first take out the venous cannulas, leaving the aortic cannula as the last to be removed. It was important that the surgeon inform the operating team when he was about to remove the cannulas, as this could cause hemodynamic changes. In addition, there could be bleeding and the patient might need to be transfused quickly through the aortic cannula.

POST-BYPASS

Once the cannulas were removed, the patient was then completely separated from the bypass machine and was considered as being 'off pump'. The surgeon would then check the suture lines for any bleeding and ensure that any shunts or other tubes were patent. If all was satisfactory, he could then begin to close the patient's chest. A chest X-ray might be taken at this time to give the surgeon and anaesthetist information about the condition of the lungs and the placement of tubes and lines. At the same time, the nursing staff would complete their charting and phone the intensive care unit to inform them as to the expected time of arrival of the patient and the patient's general condition.

The post-surgical phase

In the post-surgical phase, the patient would be prepared for transport to the intensive care unit. Once the anaesthetist and surgeon had determined that the child was stable enough to transfer, the patient would be moved to the unit and cared for there.

POST-SURGICAL CARE

The NICU and the PICU

After an operation, the patient was taken to an intensive care unit. There were two ICUs where pediatric cardiac cases might be sent: the neonatal intensive care unit (NICU) and the pediatric intensive care unit (PICU). Both units were staffed by specially trained intensive care nurses and each had a doctor on duty who specialized in intensive care medicine.

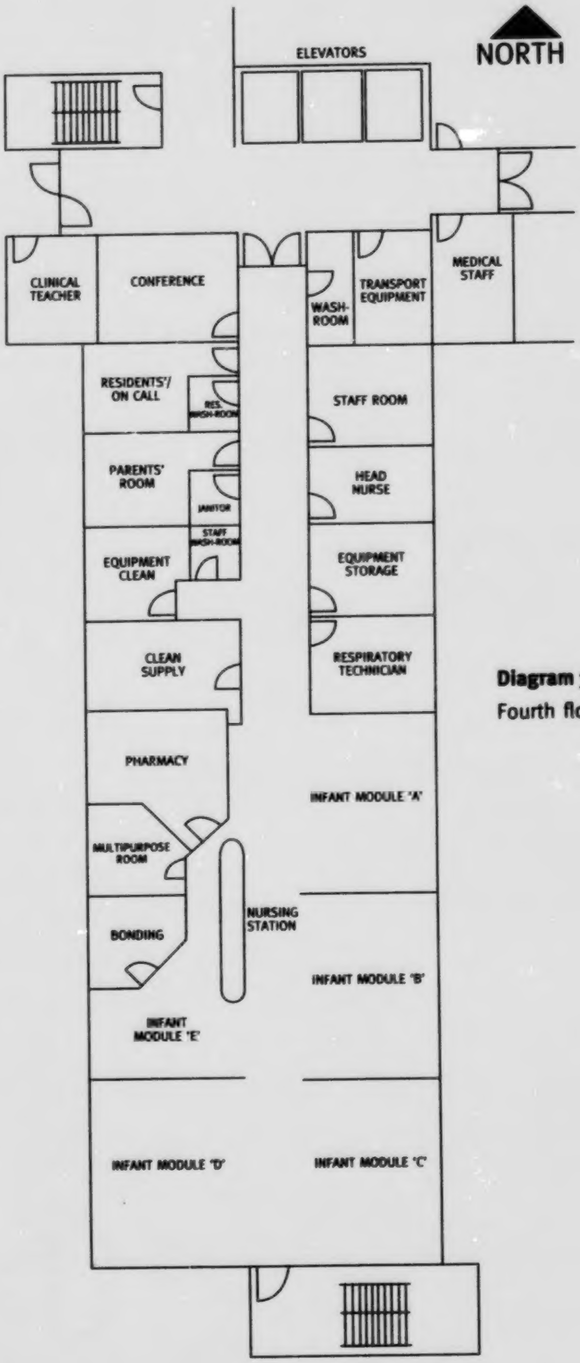
ELEVATORS
NORTH
CLINICAL TEACHER
CONFERENCE
WASH-ROOM
TRANSPORT EQUIPMENT
MEDICAL STAFF
RESIDENTS'/ ON CALL
RES. WASH-ROOM
STAFF ROOM
PARENTS' ROOM
JANITOR
HEAD NURSE
STAFF WASH-ROOM
EQUIPMENT CLEAN
EQUIPMENT STORAGE
CLEAN SUPPLY
RESPIRATORY TECHNICIAN
PHARMACY
INFANT MODULE 'A'
MULTIPURPOSE ROOM
NURSING STATION
BONDING
INFANT MODULE 'B'
INFANT MODULE 'E'
INFANT MODULE 'D'
INFANT MODULE 'C'

Diagram 3.5 Neonatal intensive care unit
Fourth floor, Winnipeg Children's Hospital

The NICU

The neonatal intensive care unit (NICU) at the Health Sciences Centre was built in 1985 on the fourth floor in the older part of Children's Hospital, one floor above the Pediatric Intensive Care Unit and the Children's Hospital's operating rooms. The NICU was an eighteen-bed unit that provided intensive care for babies less than six weeks of age.

The NICU medical staff consisted of doctors, referred to as neonatologists, who specialized in the care of the critically ill newborn. During 1994, staff neonatologists were on call in the NICU every two months for a week at a time. On-call neonatologists were responsible for all medical care within the unit, including being present for briefings when new patients were admitted, as well as monitoring any critically ill babies who needed to be managed closely.

Neonatologists in the NICU also had responsibility for the care of newborns in the intermediate care nursery at the Women's Pavilion. Staff neonatologists were expected to provide medical care on the Pavilion's labour floor and in the resuscitation room if required. To meet the demands associated with those responsibilities, there were two neonatologists on call in the NICU at all times, one of whom was usually a resident.

Pediatricians whose patients were transferred into the NICU continued to be involved in their patients' care, but the NICU medical team essentially took over treatment of the child.

The PICU

The pediatric intensive care unit (PICU) was located on the third floor in the south wing of the old part of Children's Hospital, just down the hall from the operating room. The PICU had a total of thirteen beds: eight for acute care patients and five for chronic patients. The unit dealt with children aged from six weeks of age to eighteen years of age.

Critically ill patients received one-to-one nursing care, while for other less ill children the ratio was two-to-one. The area for chronic patients was also called the pediatric extended care unit (PECU). This was separated from the rest of the PICU by a door.

Both the PICU and the NICU were staffed by persons with specialized training and dealt with children with a wide range of serious medical problems. Care was not restricted only to children who had undergone pediatric cardiac surgery. In addition, while certain procedures could be performed in the units, the units had to be specially prepared—for example, by obtaining all necessary equipment.

Preparing for intensive care

Up to one hour might pass from the time the patient's chest was closed until the patient was delivered to the intensive care unit. A bed would be brought from the ICU for the patient, rather than moving the patient to a stretcher and then to a bed in the ICU. The patient was carefully moved from the operating table to this ICU (portable) bed. Part of the difficulty in moving the patient was that each patient usually had six or more monitoring lines. The OR staff would detach the lines from the monitors and then reattach them to portable monitors. After this was done, the anaesthetist needed to check the various monitor readings and alter drug therapies in response to any changes in the patient's condition.

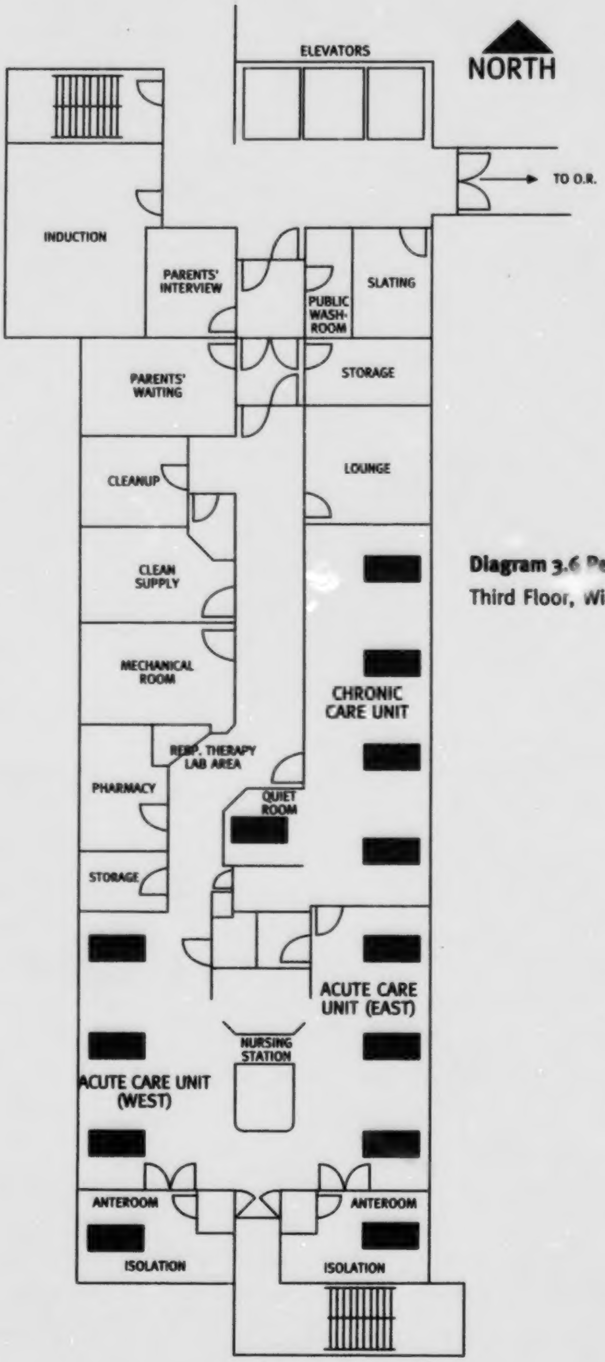
ELEVATORS
NORTH
TO O.R.
INDUCTION
PARENTS' INTERVIEW
PUBLIC WASH-ROOM
SLATING
PARENTS' WAITING
STORAGE
CLEANUP
LOUNGE
CLEAN SUPPLY
MECHANICAL ROOM
CHRONIC CARE UNIT
RESP. THERAPY LAB AREA
PHARMACY
QUIET ROOM
STORAGE
ACUTE CARE UNIT (EAST)
NURSING STATION
ACUTE CARE UNIT (WEST)
ANTEROOM
ANTEROOM
ISOLATION
ISOLATION

Diagram 3.6 Pediatric intensive care unit
Third Floor, Winnipeg Children's Hospital

Before the patient left the OR, the nurses would phone ahead and brief the ICU as to the outcome of the operation and what preparations needed to be made to receive the patient. The transfer of the patient from the operating room to the ICU was done under the supervision of the anaesthetist, who continued to monitor the patient until the ICU staff assumed care and responsibility.

Transfer to the Intensive Care Units

After the patient arrived in the ICU, an assessment was quickly made to determine stability of the child's condition. All lines were connected to permanent monitors in the unit. Some patients might be breathing on their own by that time and could have the ventilation tube removed (or be 'extubated'). In more complex cases, the patients would continue to need artificial ventilation. After vital signs were measured, reports were given to the ICU staff. If the patient was stable, the operating team would hand over responsibility for the child. If the patient was not stable, the operating team would usually continue to participate in care.

Responsibility for care

Only medical staff from the intensive care unit could write medical orders for patients transferred into the ICU. This policy was put in place in order to avoid the potential for confusion and danger that could arise in the event of conflicting directions written by separate doctors. Private pediatricians or consultants were allowed to note in the chart what they wanted done for their patients, but before any treatment was carried out by a nurse or a resident in the unit, such a request had to be confirmed by a staff doctor. If there was disagreement over a particular course of treatment, doctors, as professionals, were expected to work their problems out. However, if there was ongoing disagreement, the unit doctors would make the final decision about treatment.

Chapter 4

THE HEALTH SCIENCES CENTRE

ESTABLISHMENT OF THE HEALTH SCIENCES CENTRE

The events that are the subject of this Inquest occurred at the Children's Hospital during 1994. The Children's Hospital is part of the Health Sciences Centre (HSC), which is Manitoba's largest hospital. Through its affiliation with the University of Manitoba, the HSC is also Manitoba's primary medical teaching facility.

The HSC came into existence in February 1973, when *The Health Sciences Centre Act* (see *SM 1998-99* c.41) was proclaimed, incorporating the Winnipeg General Hospital, the Women's Pavilion, the Children's Hospital of Winnipeg, the Manitoba Rehabilitation Hospital and the D. A. Stewart Centre (Respiratory Hospital) into one administrative and legal unit. The purpose of the merger was to produce global hospital planning, uniting these facilities under a single administration. A separate affiliation agreement was signed with the Manitoba Cancer Treatment and Research Foundation.

Until the amalgamation, the Children's Hospital had been a stand-alone institution, complete with its own corporate structure, board, budget and administration.

Under *The Health Sciences Centre Act*, the Women's Pavilion became known as the Women's Centre, the Winnipeg General Hospital became the General Centre and the Children's Hospital became the Children's Centre. The medical staff of the Children's Hospital was reorganized as the Department of Pediatrics and Child Health within the HSC, and the head of the Children's Hospital became the Head of Pediatrics and Child Health.

Despite the amalgamation, however, the Department of Pediatrics and Child Health and the Children's Centre are still referred to as the Children's Hospital (or simply the Children's). Those references will occur throughout this report, but it must be kept in mind that, during the period under discussion, the Children's Hospital was not a stand-alone institution.

This chapter outlines the overall structure of the HSC during 1994, with a particular focus on those units and departments associated directly or indirectly with pediatric cardiac surgery. Changes to the hospital's organizational structure that occurred during 1993–94 are discussed, along with their implications for the pediatric cardiac program. This chapter also highlights a number of committees and procedures that relate to the monitoring and maintenance of medical care.

In some sections a certain degree of ambiguity and confusion regarding lines of authority and responsibility will be apparent. During the course of hearings, witnesses gave differing accounts of what the responsibilities of various staff appointees were. Indeed, in some cases the appointees or staff people themselves expressed uncertainty about the full range of their own responsibilities and obligations. These matters will be dealt with in subsequent portions of the report. This chapter is meant to be an overall guide to the HSC's structures.

THE 1994 HSC REORGANIZATION

During 1993–94 the HSC undertook a major organizational review. Throughout this period, lines of authority were shifting. In June 1994, a major structural reorganization occurred that, among other things, saw the number of vice-presidents reduced from seven to four and a dramatic alteration in reporting lines. This reorganization was part of a larger reorganization that had been initiated by the Manitoba government in the early 1990s. At that time the government had hired the American Patient Management group (APM) to undertake a review of the operations of a number of Winnipeg health-care institutions. The review was headed by U.S. health-care consultant Connie Curran. One of the major thrusts of this review was to reduce health-care costs.

The restructuring involved the establishment of a number of 'patient improvement teams' (PIT teams) throughout the hospital. Each team was given a dollar figure goal and expected to find ways to reduce spending by that amount in the team's area. The Inquest was told that the team examining the in-patient budget (the amount spent treating patients in the hospital) was expected to find between $10 and $15 million worth of savings, approximately ten per cent of the total in-patient budget.

The review process began in the summer of 1993 and continued until the end of the year, with a staged implementation commencing in 1994. Many people who appeared before this Inquest indicated that the review process consumed a great deal of their time and energy during that period. The review naturally created serious anxieties for many hospital personnel. Their concerns were justified. The in-patient review that was expected to save $10 million looked almost solely at staff and service-delivery areas. In other words, the changes that came from its recommendations involved either altering people's jobs or eliminating positions.

ADMINISTRATIVE STRUCTURE

THE BOARD OF DIRECTORS OF THE HOSPITAL

The board of the HSC in 1994 had 19 members. Five members were appointed by the Manitoba Government, two by the University of Manitoba Board of Governors, one by the Manitoba Cancer Treatment Centre and Research Foundation, one by the Children's Hospital Research Foundation and eight by the board itself. In addition, by virtue of their offices, the Dean of Medicine of the University of Manitoba and the President of the Medical Staff (representing doctors) sat as full voting board members. No active member of the hospital nursing staff sat on the board.

THE PRESIDENT

In 1994, the President of the Health Sciences Centre was the Chief Executive Officer of the HSC and was responsible for the proper management of all aspects of the hospital's activities. The President was appointed to his position by the board. The President's job description set out the following principal functions:

> The President is responsible for developing and maintaining a suitable organization structure and employing competent executive staff. He assists and guides the Board of Directors in setting the strategic direction for the hospital and ensures that objectives are met. He is the principal trustee of the hospital's financial and physical resources.
>
> The President sets the standards and principles which determine how the hospital is to conduct its affairs. He ensures that the hospital is in compliance with all relevant statutes and regulations and is the principal management contact for external agencies, organizations and companies. He is responsible for the development and maintenance of a sound image of the hospital in the general public. (Exhibit 375)

Although not a board member, the President attended all meetings of the hospital board, and was responsible for ensuring that the board was kept informed of matters that were within its purview. The hospital's vice-presidents and senior managers reported to the President. During 1994, the period when the 12 deaths under investigation occurred, the President of the HSC was Rod Thorfinnson. An experienced administrator, Thorfinnson was not a doctor.

THE VICE-PRESIDENTS

The HSC's vice-presidential structure was significantly altered by the corporate reorganization of June 1, 1994. Not only was the number of vice-presidents reduced, but the portfolio system that had been in place was eliminated and replaced by a system of program management.

Vice-presidents and portfolios before June 1994

Before the reorganization, the HSC had seven vice-presidents, each with a specific portfolio or area of responsibility. The portfolios were:

- Corporate planning
- Medical
- Nursing
- Operations
- Finance
- Human resources
- Communications and information systems (This Vice-President reported to the Senior Vice-President for Corporate Planning.)

Some of these portfolios, such as Medicine and Nursing, were known as clinical portfolios, while others, such as Finance or Operations, were known as non-clinical portfolios. There was also a vice-presidential hierarchy: four vice-presidents were titled senior vice-presidents. Under this system a person would hold a position with a specific title, such as Senior Vice-President, Medicine; or simply Vice-President, Communications and Information Systems. All but one of the vice-presidents reported directly to the President and all were appointed by the board.

The significant portfolios before June 1994 in terms of the issues under consideration by this Inquest were the Senior Vice-President Medical (a position held by Dr. J. B. (Ian) Sutherland) and the Senior Vice-President Nursing (a position held by Susan VanDeVelde-Coke). Under this structure, Sutherland also chaired the Medical Advisory Committee (an important hospital committee that will be discussed later).

Before discussing the 1994 reorganization, it is useful to outline the structure of these two portfolios (Medical and Nursing) before their elimination in June 1994.

The medical portfolio

The Senior Vice-President (SVP) Medicine was responsible for the Medical Portfolio. This portfolio supervised services delivered by the hospital's medical staff. (In this context, medical staff included doctors, dentists and scientists). The Medical Portfolio was subdivided into departments, each with its own head or chief, who was appointed by the board. Before June 1, 1994, all department heads reported to the SVP Medicine. All doctors with HSC medical appointments would have an appointment to one of the medical departments.

The medical departments at the HSC were:

- Anaesthesia
- Clinical Chemistry
- Clinical Microbiology
- Community Health Sciences
- Emergency

- Medicine
- Obstetrics and Gynaecology
- Ophthalmology
- Otolaryngology
- Pathology
- Pediatrics and Child Health
- Psychiatry
- Radiology
- Surgery

The three key departments for the purposes of this Inquest were Anaesthesia, Pediatrics and Child Health, and Surgery. The structure of these departments will be discussed later in this chapter.

The nursing portfolio

Before June 1, 1994, the Senior Vice-President Nursing was responsible for the Nursing Portfolio. This portfolio was responsible for the provision and management of all nursing services in the hospital. The portfolio was divided into six smaller divisions, each with its own director. All directors reported to the SVP Nursing.

The Nursing Divisions at the HSC, before June 1994, were:

- Surgical Nursing
- Medical Nursing
- Psychiatric Nursing
- Pediatrics and Child Health
- Adult Ambulatory Care
- Obstetrics and Gynaecology

The SVP Nursing was also responsible for Nursing Education and Research. The key divisions for the purposes of this Inquest were Pediatrics and Child Health Nursing and Surgical Nursing.

The rationale for the reorganization

The portfolio system had long been criticized because people working side by side in a ward or medical unit often fell within vastly different administrative lines of authority and accountability. Doctors, nurses, medical technicians, residents, therapists and administrative personnel, working on the same ward and dealing with the same patients, reported to different managers and responded to different managerial priorities. Unit personnel could easily fail to develop a team approach to the management of the issues that occurred in the unit. This sometimes resulted in conflicts over the medical management of patient care that required the involvement of senior managers for resolution.

The reorganization sought to break down these barriers by creating lines of authority that grouped the individuals who worked together on the same ward or in the same program into management units that reported to the same vice-president.

Vice-presidents and portfolios after June 1994

In June 1994 the system changed to one where there were only four vice-presidents, each of whom had both clinical and non-clinical responsibilities and reported to the President. The seven portfolios, including the Medical and Nursing portfolios, were eliminated. Of the four vice-presidents, the three of interest to this Inquest from June 1994 onward were Sutherland, Helen Wright and VanDeVelde-Coke.

The new structure sought to bring units together under one line of authority. No longer did all medical departments report to a single vice-president. The same was true of nursing divisions, which were renamed patient service divisions. Under the new structure, program teams were created, led by three managers with equal and joint responsibility for overseeing the program of which they were a part.

Medical departments and patient services divisions were clustered into program teams. The head of Pediatrics and Child Health and the director of Patient Services for Pediatric and Child Health were part of the Child Health Program Team and reported to Vice-President Helen Wright. (The third member of the Child Health program team was the director of Support Services, an administrative officer.)

Medical departments that were interdependent reported to the same vice-president. For example, the two other medical departments key to this Inquest, Anaesthesia and Surgery, reported to VanDeVelde-Coke.

Program teams were responsible for patient care teams. In the case of the Child Health program team, the significant patient care teams for this Inquest were those for Surgery, Pediatric Intensive Care and Neonatal Intensive Care. Patient care teams were meant to bring together front-line and administrative staff. These teams were to be made up of a section head (a senior doctor responsible for a medical service), a unit manager (usually a senior nurse) and an administrative official.

The hospital's bylaws were not updated at the time of the reorganization. As a result, the bylaws continued to refer to the responsibilities of non-existent positions, such as Senior Vice-Presidents.

Issues raised by the reorganization

The positions of Vice-President Medicine and Vice-President Nursing had always been held by persons with medical and nursing backgrounds respectively. The elimination of these positions caused some concern among staff that medicine and nursing—and nursing in particular—would lose status. Therefore, Thorfinnson gave a written commitment that there would always be one vice-president with a nursing background and one vice-president who was a doctor. (Other issues relating to nursing and reorganization will be discussed later in this chapter.)

MEDICAL DEPARTMENTS

For the purposes of this inquest, the three key medical departments were Anaesthesia, Surgery, and Pediatrics and Child Health. During all of 1994, Dr. Douglas Craig was the Clinical Head of Anaesthesia and Dr. Robert Blanchard was the Clinical Head of Surgery. Until June 1, 1994, Dr. Agnes Bishop was the Clinical Head of Pediatrics and Child Health (and therefore the head of the Children's Centre). She left on that date for a position with the federal government. For the summer months of 1994, the position rotated among various medical staff, including Dr. John Bowman. On September 15, 1994, Dr. Brian Postl became Clinical Head of Pediatrics and Child Health.

Before June 1, 1994, these three heads all reported to Sutherland. After that date, the heads of Anaesthesia and Surgery reported to VanDeVelde-Coke, while the head of Pediatrics and Child Health reported to Helen Wright.

According to the medical staff bylaws, department heads had the following responsibilities:

- To develop and maintain high standards of patient care, teaching and research within the department;
- To supervise the work of departmental members in all matters relating to patient care;
- To prepare a departmental budget when called upon to do so and maintain expenditures within that allocated budget;
- To develop departmental policies in consultation with the Department Council;
- To act as the official channel of communication between the administration and the department;
- To report to their respective VP on the work of the department when called upon to do so;
- To conduct investigations of departmental members, or assign such investigations as required within medical staff disciplinary procedures;
- To recommend to the Board, through the Medical Advisory Committee, the appointment, reappointment, delineation of privileges and other changes in status of departmental members;
- To recommend to the Board, through their respective VP and the President, the appointment, reappointment or termination of section heads.
- To immediately suspend, or otherwise limit, the privileges of a member of the department, for a period of up to 10 working days, for conduct that the department head reasonably believed might negatively affect patient care or which constituted a serious breach of ethical standards, or breached Centre policies and procedures; and
- To exercise such other powers and perform such other duties as might from time to time be conferred by the Board.

Surgical sections

There were a number of sections within the Department of Surgery. They all reported to Dr. Robert Blanchard, the head of surgery in 1994. Each section had its own section head, and each subsection also had a subsection head. For the purposes of this Report, the primary section of interest is the Section for Cardiovascular and Thoracic Surgery and the Pediatric Cardiac Surgery service within it.

Cardiovascular and Thoracic Surgery

The Department of Surgery had a section known as Cardiovascular and Thoracic (CVT) Surgery, with a section head. During 1994 the acting head of the CVT section was Dr. Helmut Unruh. The pediatric cardiac surgeon, Dr. Jonah Odim, reported to Unruh, who reported to the head of surgery. Odim was referred to as a service chief for Pediatric Cardiac Surgery. A service in a hospital consists of a group of doctors providing the same kind of medical service. Each service is usually assigned a number of residents, interns and medical students who are posted there for a period of time. However, the pediatric cardiac surgical service headed by Odim was not so fortunate. For all intents and purposes, Odim was the only member of the pediatric cardiac surgery service and had no residents assigned to him for training as pediatric cardiac surgeons. However, residents did occasionally provide assistance at pediatric cardiac operations.

Odim's contract specified that he was being offered a position as associate professor in the Department of Surgery of the Faculty of Medicine, University of Manitoba, as well as a position on the medical staff of the Health Sciences Centre. In the former position, he was responsible to the head of the Department of Surgery. The contract stated that in relation to his duties on the medical staff:

> You will undertake the responsibilities of Service Chief, Pediatric Cardiac Surgery at the Health Sciences Centre . . . and other duties as assigned by the Section Head, Cardiothoracic Surgery, under the Surgeon-in-Chief, HSC. (Exhibit 178)

Odim's job description included the following passage:

> 1. Title: Service Chief, Pediatric Cardiac Surgery
>
> 2. Responsible to: Section Head, Cardiovascular & Thoracic Surgery
>
> 3. Description of area of responsibility
>
> a. General Purpose of Program
>
> To provide the citizens of Manitoba with a high standard of care and specialty expertise in the area of pediatric cardiothoracic surgery. This program is partly supported by the Variety Children's Heart Centre which is primarily an ambulatory service providing consultations on a referral basis, to pediatricians and family practitioners throughout the Province of Manitoba and Northwestern Ontario; occasional referrals are received from the eastern part of Saskatchewan. Children with significant heart lesions are followed on a regular basis before and after heart surgery.
>
> As the surgical component of the service expands there is increasing hospital involvement, although as a rule the in-hospital commitment is in consultation on the wards and Intensive Care Unit of the Children's Hospital. Other nurseries and pediatric units in city hospitals are visited in consultation on occasion.
>
> Nursing staff and technologists work both in the Heart Centre itself and in the heart catheterization laboratory (which is located in the Radiology Department of the Children's Hospital), as well as providing services on the wards of the Children's Hospital. There is considerable after-hours activity, with physicians, nurses and technologists providing 24 hours hospital coverage, seven days a week.
>
> The Heart Centre itself incorporates examination rooms and the non-invasive laboratories, where electrocardiography (ECG), echocardiography (echo) and exercise testing is performed. A 'drop-in' service for ECG's is provided for city practitioners, otherwise these laboratories support only the clinical activities of the Heart Centre staff.

> b. Area of Responsibility
>
> Responsible to organize and direct a broad spectrum of pediatric cardiac services and to promote a high standard of patient care, teaching and research activities. The Service is also responsible for directing the surgical component of the Variety Children's Heart Centre. (Exhibit 178)

Odim also held a secondary hospital appointment in the Department of Pediatrics. However, the Pediatric Cardiac Surgery Program was primarily a surgical (as opposed to a pediatric) program.

Pediatric sections

There were also a number of sections within the Department of Pediatrics and Child Health that reported to the head of that department. For the purposes of this report, the sections with which we are most concerned are Pediatric Cardiology, Pediatric Surgery, Pediatric Intensive Care and Neonatal Intensive Care.

Pediatric cardiology and the Variety Children's Heart Centre

Pediatric Cardiology services were delivered through the Variety Children's Heart Centre. In 1994, the acting medical director of the VCHC and the acting section head of Pediatric Cardiology was Dr. Niels Giddins.

According to a job description dated October 1993 and prepared by the previous VCHC medical director, Dr. George Collins, the medical director of the VCHC was required to:

> Provide overall supervision of the medical diagnostic and therapeutic activities occurring at Variety Children's Heart Centre and Children's Hospital, ensuring the highest possible standard of care
>
> With the Surgical Director [of the VCHC], and Directors of the Cardiac Catheterization and Non-Invasive Laboratories:
>
> > Develop and maintain appropriate guidelines for pre-operative evaluation, perioperative care, and post-operative management of children referred for congenital and acquired heart disease
> >
> > Maintain free and open communications with other sections (i.e. Neonatology, Intensive Care) and departments including (i.e. Anaesthesia, Radiology) within Children's Hospital, Health Sciences Centre, and the University of Manitoba
> >
> > Oversee staffing assignments within VCHC
> >
> > Establish standards for staff safety and conduct. (Exhibit 71)

Pediatric surgery

Pediatrics and Child Health also had a section known as Pediatric Surgery. Dr. Nathan Wiseman was the head of Pediatric Surgery during this period. He reported to the head of Pediatrics, as well as to the head of Surgery (Exhibit 296). His responsibilities consisted primarily of co-ordinating the surgical services provided by the Children's Centre, ensuring that the scheduling of cases occurred in an appropriate manner and that the operating rooms at the Children's Hospital were properly used.

Wiseman's job description stated that he was "responsible to: Department Head, Department of Surgery and the Department of Pediatrics and Child Health." Under the heading of "Description of Area of Responsibility," the job description stated:

> To provide the citizens of Manitoba with a high standard of care in areas of Pediatric Surgery.
>
> b) Area of Responsibility
>
> Responsible to organize and direct a broad spectrum of pediatric surgical programs and to promote a high standard of patient care, teaching and research in the field of Pediatric Surgery. Overall, Pediatric Surgery includes Pediatric Ophthalmology and Pediatric ENT as it impacts on Pediatric Surgery.
>
> c) No. of physicians:
>
> CVT 3, Dentistry 11, Plastics 3, Urology 3, Neurosurgery 5, General Surgery 4, Ophthalmology 8, Orthopaedics 5, Otolaryngology 12. (Exhibit 296)

Under the heading of "Personnel," it stated that the head of Pediatric Surgery:

> Coordinates the selection process and recommends to the Department Head office the appointment of and reappointment of staff who are adequately qualified to deliver a high standard of care, research and education in the different specialty areas. (Exhibit 296)

Pediatric Intensive Care

Pediatrics and Child Heath had a section known as pediatric intensive care. This section was always referred to as the pediatric intensive care unit (PICU). The head of the PICU in 1994 was Dr. Murray Kesselman. The doctors who worked in the unit were referred to as intensivists and specialized in the treatment of intensive care for children from the age of six weeks to 18 years. The other intensivists who worked in the unit during 1994 were Dr. Fiona Fleming, Dr. B. J. Hancock and Dr. Jo Swartz. Hancock also worked in the Department of Surgery as a pediatric surgeon and Swartz was also an anaesthetist and was a member of the Department of Anaesthesia.

A description of the services provided in this unit is found in Chapter Three.

Neonatal Intensive Care

Pediatrics and Child Health had a section known as neonatal intensive care. This section was always referred to as the neonatal intensive care unit (NICU). The doctors who worked within it were referred to as neonatologists and had been trained in the special care of newborn children aged up to six weeks. In 1994, the head of this section was Dr. Molly Seshia. The other neonatologists were Dr. J. Belik, Dr. R. Caces, Dr. O. Casiro, Dr. R. Alvaro, Dr. H. Rigatto, Dr. C. Fajardo, Dr. G. Cronin and Dr. R. Savani.

A description of the services offered by this section is found in Chapter Three.

Anaesthetic sections

The Department of Anaesthesia was responsible for providing anaesthetic services within the hospital. The head of the Department of Anaesthesia was Dr. Douglas Craig. The department had two sections, one for adult anaesthesia and one for pediatric anaesthesia. Both sections reported to the head of Anaesthesia.

Pediatric anaesthesia

The head of the section of pediatric anaesthesia was Dr. Suzanne Ullyot. The section provided anaesthetic coverage for all surgical and some diagnostic procedures involving pediatric patients in the hospital. There was also a pediatric cardiac anaesthesia subsection.

Pediatric cardiac anaesthesia

The subsection of pediatric cardiac anaesthesia was responsible for providing all anaesthetic coverage for pediatric cardiac patients at Children's Hospital during 1994. The subsection did not have a subsection head until May 16, 1994, when Dr. Ann McNeill was appointed to that position. She reported to Ullyot. Four specialists provided pediatric cardiac anaesthetic care during 1994: McNeill, Dr. Jo Swartz, Dr. Heinz Reimer and Dr. Harley Wong.

MEDICAL STAFF

Health-care professionals, such as doctors, were appointed to the HSC's medical staff. As such they were not employees, but were professionals with a hospital appointment. They had hospital privileges, which meant that they were allowed to work in the hospital. As will be seen later in this report, professionals with a hospital appointment enjoyed a degree of autonomy that employees such as nurses did not enjoy.

Every member of the medical staff was appointed to a specific department. However, staff members could have more than one appointment. In such cases, the member had a primary appointment and a secondary appointment.

The medical staff was governed by the HSC's medical staff bylaws. (Exhibit 41) According to these bylaws, the medical staff were responsible:

- for ensuring the provision of optimal medical care to patients at the Centre, of a standard commensurate with the resources available and the state of medical science;
- for ensuring an environment conducive to scholarly inquiry and research at the Centre;
- for ensuring the provision of medical education programs to support the aim of a high standard of care; and
- for advising the Board on medical matters relating to the mission, role, goals and objectives of the Centre.

To accomplish this, the medical staff was expected to maintain an effective system for making recommendations for the appointment, reappointment and the delineation of privileges. In addition, the bylaws stated that the medical staff should:

> Maintain an acceptable quality assurance programme for the Medical Staff through the establishment of standards of medical care in the Centre, the monitoring of performance, the identification of problems, and the undertaking of corrective action in relation to the conduct of medical practice in the Centre. (Section 3.2.2.2)

In short, the medical staff were responsible to the board for the "quality of patient care, education and research." (Section 4.1.11)

Members were appointed and reappointed to the medical staff on the basis of the recommendation of the Medical Advisory Committee. This committee made its decision based on applications submitted to it by the appropriate department head. According to the medical staff bylaw, Section 5.2.21,

> All medical practitioners shall be qualified to practice in the Province of Manitoba and shall be registered and hold a current license with the College of Physicians and Surgeons of Manitoba.

In addition, the board, when deciding on an application, considered past performance in quality of patient care, ability to work with colleagues and staff, and contribution to administration and committee work.

Members of a department were responsible to the section head and the department head for meeting standards of patient care, performance of teaching and research duties, performance of administrative responsibilities, and appropriate attendance at meetings.

Each department was expected to have its own Department Council to act as a forum for communication and discussion between the department head and members of the department. As well, the Department Council could:

> Establish such standing or ad hoc committees as it deems necessary each operating within specific terms of reference. Such Committees shall include a Credentials and Privileges Committee and a Standards Committee. [Section 6.6 (e)]

The Department Council comprised all members of the department (except for honourary and educational members) and persons who the council believed might be appropriately included in membership because of their association with the department.

Medical Staff Council

The Medical Staff Council was composed of the medical staff at the Centre and was intended to represent the interests of the medical staff. The council consisted of members of the active staff, members of the provisional staff and members of the scientific staff.

Medical Advisory Committee

The Medical Advisory Committee was the senior patient care committee responsible for advising the board on all matters concerning medical policy and issues.

According to the HSC bylaws, the main duties of the Medical Advisory Committee included:

- advising the board on all matters concerning patient care policy and issues;
- establishing and maintaining standards of medical practice;
- through the President of the Medical Staff Council informing the medical staff of business transacted at meetings of the Medical Advisory Committee;
- making recommendations to the board concerning the qualifications required for appointment to the medical staff;

- making recommendations to the board on the appointment and privilege delineation of each member of the medical staff; and
- recommending to the board policies and procedures relating to disciplinary matters.

The Medical Advisory Committee's membership included a Senior Vice-President, who acted as the chair. (Both before and after June 1, 1994 this position was occupied by Sutherland.) Other members included the President of the Medical Staff Council, three other officers of the Medical Staff Council, the department heads of the various medical departments and the Dean of the School of Medicine. The committee's non-voting members included the President of the HSC, the Senior VP of Operations, Senior VP of Nursing, Senior VP of Corporate Planning, the HSC Director of Research and the Director of Medical Administration. The Medical Advisory Committee met at least ten times a year.

Remuneration

HSC medical staff received their income in a variety of ways, besides the payment they might receive from the University of Manitoba for their academic duties. Department heads, section heads and subsection heads were paid by the HSC. In addition, they were entitled to bill the Manitoba government for medical services that they performed in the hospital. Surgeons, anaesthetists and other doctors similarly received a combination of direct payments and fee-for-service payments.

The members of the section of pediatric anaesthesia had established an arrangement with the hospital that introduced an element of income sharing to the manner of their remuneration. Essentially, members of the section performed their services and each was paid on the basis of the earnings received by the entire section (less an administrative fee).

NURSING

The greatest impact of the administrative changes that occurred at the HSC in 1994 was with respect to nurses. Up until June 1994, as noted above, there was a Nursing Portfolio with a number of divisions. Each division had its own director, each of whom reported to the Senior Vice-President Nursing.

Under the June 1994 reorganization, Nursing as a separate portfolio disappeared. In the new system the nursing divisions were renamed patient service divisions, and the directors of these divisions reported to different vice-presidents. For the purposes of this Inquest, there was one significant nursing division or, after June 1, patient service division. That was the Division of Pediatrics and Child Health Nursing, which became the Patient Service Division (Pediatrics and Child Health).

The Division of Pediatrics and Child Health Nursing – Patient Service Division (Pediatrics and Child Health)

Isobel Boyle was the Director of Pediatrics and Child Health Nursing at the Children's Centre before June 1, 1994, when her title changed to Director of Patient Services (Pediatrics and Child Health). Whereas before June 1, 1994, Boyle had reported to Senior Vice-President Nursing VanDeVelde-Coke, after the reorganization she reported to Vice-President Wright, who also had responsibility for the Medical Department of Pediatrics and Child Health.

Through 1994 Boyle was responsible for 450 nursing positions. Because part-time employees filled many of these positions, the Director was responsible for between 600 and 700 people.

Nursing assignments were organized into units, each with a unit manager (formerly called the head nurse). While unit managers continued to perform most of the roles carried out by head nurses, the job (at least as formally described) was now refocused away from nursing to patient services and management responsibilities.

The training that nurses received emphasized the importance of dealing with any concerns they might have about medical quality through the appropriate channels. This would involve raising the matter with their unit manager, who was expected to take the concern to the next level.

Nurses from the following areas were involved with the Pediatric Cardiac Surgery program in 1994:

Nurses at the Variety Children's Heart Centre

Two nurse clinicians worked at the VCHC. Lois Hawkins, the senior nurse clinician at the VCHC, reported to Isobel Boyle.

Operating room nurses

Karin Dixon was the head operating room nurse until June 1, 1994. From that date forward, she was referred to as the unit manager. She reported to Isobel Boyle.

Carol Youngson was the senior nurse in charge of cardiac surgery. Youngson was responsible for ensuring that all supplies and equipment were ordered and for co-ordinating the surgical schedules of the other cardiac nurses. She reported to Karin Dixon.

Anaesthetic nurse

The only anaesthetic nurse was Irene Hinam. She reported to Boyle before June 1, 1994. After the reorganization she reported to Dixon.

Pediatric intensive care nurses

Until July 1994, Donna Feser was the PICU acting head nurse (and after June 1, 1994, the unit manager). In July, Evelyn Link returned from leave and resumed her position as unit manager. Both Feser and Link reported to Boyle.

Neonatal intensive care nurses

Sybil Russell was the head nurse and then the unit manager in PICU during the period under discussion. She reported to Boyle.

The Nursing Council

Before the change of June 1, 1994, there had been a Nursing Advisory Committee in place at the hospital that oversaw nursing issues. The VP Nursing sat on the Committee, which had significant status and authority within the hospital over the regulation of the nursing profession. For example, the Nursing Advisory Committee had a quality assurance subcommittee, which addressed quality assurance issues from a nursing perspective. With the changes brought about on June 1, the Nursing Advisory Committee was eliminated.

As noted above, the restructuring also removed the word "nursing" from the hospital's formal organization and vocabulary. Directors of nursing became directors of patient services, while head nurses became unit managers. Under the new structure, the hospital did not have to have nurses in any position above the level of clinical resource nurse (formerly called a senior team leader), which is one level below a unit manager. The doctors continued to be recognized organizationally through the Medical Advisory Committee. In response to these concerns, a Nursing Council was established at the hospital.

The Nursing Council was charged with:

- Facilitating the growth of professional nursing at the HSC;
- Ensuring that patient care provided by nursing services was consistent with the HSC Mission Statement and Philosophy of Nursing;
- Fostering consistency in application of nursing policies and procedures;
- Setting directions for nursing education, research and clinical practice; and
- Facilitating communication between clinical programs.

The committee's membership comprised the six directors of patient services, two nurses from each of the clinical programs, and one representative each from the School of Nursing, and Nursing and Education Research, Nursing Systems. In addition, the chairs of the Educational Advisory Committee, the Nursing Practice Committee, the Nursing Policy and Procedure Committee and the Nursing Research Steering Committee were members of the council. The President of the Hospital was an *ex officio* member. The Nursing Council met once a month and was responsible for addressing issues of professional practice, education and research. (Exhibit 312)

PERFUSIONISTS

Perfusionists are the technicians who run the cardiopulmonary bypass machine. Perfusion Services was a technical department that reported to the head of surgery, and provided perfusion services for adult and pediatric surgery. Michael Maas was the head of Perfusion Services at the HSC. He and three other perfusionists (Chris McCudden, Todd Koga and David Smith) provided perfusion services at both the HSC and St. Boniface General Hospital.

STAFF DISCIPLINE

The HSC board had the right to appoint, suspend or remove all medical and other staff and employees.

The board required that complaints alleging misconduct against a member of the medical staff be in writing and detail the specific misconduct alleged. Complaints were to be sent to the President or the appropriate vice-president. These complaints could be forwarded to the appropriate department head for informal resolution. If the complaint involved the department head, the Senior Vice-President Medical would deal with it.

Where the informal process failed or the complaint was deemed to be of a serious nature, the complaint was handled by the complaints committee of the Medical Advisory Committee. The committee investigated the complaint and, if it deemed necessary, struck a hearing panel. The panel's report was forwarded to the board, which decided on the course of action to be followed.

In addition, a department head had the right at any time to immediately suspend, or otherwise limit, the privileges of a member of the department, for up to 10 working days, for conduct that the head reasonably believed might negatively affect patient care or would constitute a serious breach of ethical standards (Exhibit 41, section 9.5.51).

In such a situation, the department head was required to initiate a complaint and inform the SVP.

COMMITTEES WHOSE ACTIVITIES TOUCHED UPON THE EVENTS OF 1994

The HSC had a dense committee structure, and the following is not an exhaustive listing of the HSC committees. However, it does outline a variety of institutional committees that either became involved in the events of 1994 or might have been expected to become involved in those events.

THE PEDIATRIC OPERATING ROOM COMMITTEE

The HSC had a Pediatric Operating Room Committee that was responsible for dealing with day-to-day operating room problems as they related to the smooth and efficient operation of the operating room and its environs. Matters that related directly to nursing, anaesthesia and surgery were to be dealt with primarily by those departments, but where co-ordination and interaction between the disciplines was an issue, the Operating Room Committee was expected to address such problems directly (Exhibit 309).

The committee was made up of the OR head nurse, the head of Pediatric Surgery, the head of Pediatric Anaesthesia, a pediatric surgeon elected by the Pediatric Surgical Council and the Administrator of Children's Hospital. The committee was to meet on a monthly basis.

THE CHILDREN'S HOSPITAL MANAGEMENT ADVISORY COMMITTEE

This Committee existed to provide a forum for patient care teams to discuss common issues, advocate for needed resources, approve standards and guidelines, and co-ordinate activities. The committee's members comprised the clinical director, director of patient services, the director of support services, one representative from each of the patient care teams and one representative each from Medical Information, Radiology and the Family Advisory Committee. One of the committee's responsibilities was to ensure quality monitoring for the child health program.

QUALITY ASSURANCE

The HSC, as a large medical institution, made use of a variety of committees and practices to review quality assurance issues, such as patient care and patient outcomes. The following list outlines the main committees that were or might have been expected to become involved in the events of 1994.

QUALITY ASSURANCE COMMITTEE

The HSC had a Quality Assurance Committee that was required to meet at least four times a year. The members were appointed by the board and included the Chairman of the Medical Staff Council. Non-voting members of the committee include the President and three vice-presidents.

The committee was charged with ensuring that:

- A quality assurance program was established and met the requirements as set out in the Canadian Council on Hospital Accreditation Standards Manual;
- Standards for patient care delivery were defined;
- Established standards were appropriately monitored;
- Quality assurance activities were recorded and outcomes reported; and
- Adequate resources were allocated to undertake the activities of the program.

The committee was required to report monthly to the board. The quality assurance program was meant to deal with broad issues on a retrospective basis, rather than deal with specific problems in specific units.

MORBIDITY AND MORTALITY (M & M) ROUNDS

Morbidity and Mortality Rounds were meetings at which incidents, particularly deaths, would be given a detailed review. Pediatric cardiac surgery Morbidity and Mortality Rounds were to be conducted once a month to address surgical issues. The meetings were open to everyone in the hospital in addition to the surgical team and other professionals involved in the case. The CVT surgery section also conducted its own monthly M & M Rounds.

INCIDENT REPORTS

When there was an untoward event at the HSC, according to the bylaws of the hospital, staff members who had been involved in the event, witnessed the event or were advised that it had taken place were under an obligation to report the event by completing an incident report.

An incident was defined in the HSC Corporate Policy and Procedure Manual as:

> a patient care-related or non-patient care-related event which:
>
> 2.1.1 is normally not anticipated under usual circumstances and may adversely affect patient care, the provision of service, or the assets or reputation of the centre; or
>
> 2.1.2 has the potential to result in litigation. (Exhibit 107)

If the incident involved a patient, it was to be documented in the patient's HSC medical record, along with a description of the injury and the treatment. The incident report itself, however, did not become part of the patient's hospital record. Departments were expected to develop lists of reportable incidents and categorize them as being of Minor or No Consequence, Moderate Consequence or Major Consequence.

Staff were expected to take immediate remedial action, report the event to the appropriate supervisor and then fill out an incident report. This could be a general incident report, a medication discrepancy incident report, a fire and false alarm report, or a security incident report.

Supervisors were expected to investigate the incident and take the appropriate follow-up measures. Department heads were to be informed of incidents with major consequences and incident report forms were to be forwarded to department heads.

Department heads were required to take steps to prevent the recurrence of such incidents and to contact any other departments that were involved in the incident. In the case of incidents with major consequences, the department head was expected to notify the appropriate vice-president. In the case of patient-care related incidents, the head was expected to provide a copy of the report to the director of the Medical Information Department. The director of medical information was then responsible for notifying the Health Sciences Centre insurance adjuster and the hospital's legal counsel, securing the medical records, coordinating meetings, collecting information, photocopying records and corresponding with relevant parties.

There was no requirement to inform the patient or the patient's family that such a report had been filed or to provide them with a copy of the report. The patient or patient's family might be informed that an incident report had been filed. A copy of the incident report was not kept as a part of the patient's chart.

THE COLLEGE OF PHYSICIANS AND SURGEONS OF MANITOBA

The College of Physicians and Surgeon of Manitoba (CPSM) is the licensing body for physicians and surgeons in Manitoba. Pursuant to the provisions of *The Medical Act* (RSM 1987, c. M90), and various regulations and bylaws thereunder, the College of Physicians and Surgeons created a Medical Standards Committee for the Province of Manitoba. The College also established a standards committee, the Pediatric

Death Review Committee, to review all cases of pediatric deaths in the province. This committee met approximately six times a year.

The College also designated medical standard committees for each of the hospitals and/or regions of Manitoba. The Health Sciences Centre had a Medical Standards Committee (referred to as the Centre-Wide Committee) created under its bylaws. This committee oversaw medical standards for the entire hospital, including the Children's Hospital, General Centre and Women's Centre. The College had recognized the Centre-Wide Committee as the Medical Standards Committee for the Health Sciences Centre.

There also existed a Children's Hospital Standards Committee that reported to both the Centre-Wide Committee and the College's Paediatric Death Review Committee. In 1994, Dr. Milton Tenenbein chaired this committee. The Children's Hospital Standards Committee had approximately 12 members, some of whom were on the committee by virtue of their office, while others were appointed. Each committee member was a doctor who worked at Children's Hospital.

A panel of three surgeons, each of whom was appointed by the Department of Surgery, reviewed all surgical deaths at Children's Hospital. A surgical death was defined as a death of a child who had had surgery immediately before death or was admitted to hospital and died under the care of a surgeon. In 1994, Dr. Nathan Wiseman chaired this panel. The other two members of the committee were Dr. Odim and Dr. Postuma. The panel's finding would be reported to the Children's Hospital Standards Committee by Wiseman, who was also a member of the Standards Committee.

The Standards Committee would receive the panel's report and then discuss the case. In doing so the panel members might make use of personal information, information in the patient's chart, or information that had been brought forward from the panel. It was not the committee's practice to hear testimony or evidence from non-members.

Following the discussion, Tenenbein would summarize the case and forward it to the Paediatric Death Review Committee. He would also prepare a generic report that did not identify specific cases. This summary would be forwarded to the Centre-Wide Committee. From there the summary would be circulated to department heads as a part of the Centre-Wide Committee's report.

In 1994, Dr. Michael Moffat was the co-ordinator of the Paediatric Death Review Committee. He reviewed the reports from the Children's Hospital Standards Committee and other reports (such as police and child welfare reports) that may have been filed on the child's death. He then would summarize the case for the Paediatric Death Review Committee. That committee (which included in its membership not only Tenenbein, but also Wiseman and the HSC's chief pediatric pathologist, Dr. Susan Phillips) would then review the case.

The role of the hospital Standards Committee included the assessment of medical practice through peer review, analysis and education to improve, rather than to discipline. In his testimony, Tenenbein said that the Standards Committee was the only specific mechanism or program for quality assurance within Children's Hospital in 1994.

The Standards Committee filled an educational purpose in the sense that the committee investigated incidents to determine if there was anything to be learned from them. If the committee concluded that there was something to learn from a death, the chairperson then communicated the committee's conclusions to the individual, along with a recommendation either for a change in procedure or in how similar cases should be handled in the future, or for upgrading of skills.

The committee could issue a more public statement to the profession to alert it to a particular issue. The committee could also communicate with a department or the hospital about its findings, and might also communicate with the government. In all such cases, the communications were of a general nature, without specific reference to a particular patient and without identifying any of the persons involved.

Members of the general community and members of the hospital staff could also bring a particular matter to the attention of the Standards Committee. While the committee would investigate matters brought to its attention in such a manner, it did not normally communicate its results and findings back to the source of the question.

THE MANITOBA ASSOCIATION OF REGISTERED NURSES

The Manitoba Association of Registered Nurses (MARN) is the regulatory and professional body for registered nurses in Manitoba. It derives its mandate from legislation, *The Manitoba Association of Registered Nurses Act* (*RSM 1987* c. R40). The Association deals with issues relating to registration, regulation, professional conduct, health policy, education, research and nursing practice. MARN has a responsibility to protect the public from unsafe, incompetent and unethical nursing practice.

THE OFFICE OF THE CHIEF MEDICAL EXAMINER

Deaths in the HSC and other hospitals in Manitoba fell under the jurisdiction of the Office of the Chief Medical Examiner of Manitoba (CME). When a child died, the death had to be reported to the Medical Examiner's office. In the case of a hospital death, a Medical Examiner's Investigator (MEI) would go to the hospital and conduct an initial investigation. Deaths were categorized under five classifications that the CME used: natural, accidental, suicidal, homicidal or undetermined. Under the policy of the Chief Medical Examiner's office, autopsies were to be ordered when children died either during or immediately following operations. The CME's office did not order an autopsy if it had been informed that the hospital's Department of Pathology intended to perform one.

In those cases of surgical death where the cause of death was known and the parents were opposed to an autopsy being performed, the CME could agree to waive the requirement for an autopsy. For this reason, autopsies were not performed in the case of two children whose deaths were under investigation. The MEI's chief source of information in such cases was the attending surgeon.

A further investigation, conducted by a medical examiner (who must be a doctor), could be ordered. This was invariably the case when the CME's office ordered an autopsy. These were then referred to as medical examiner's cases.

An autopsy involves the examination of a dead body and its structures and organs to determine the cause of death. An autopsy is meant to observe the effects of aging and disease, and determine the evolution and mechanisms of disease processes. Doctors who have been trained in pathology carry out autopsies. The pathologist usually dissects the body and examines its internal organs.

The findings are then recorded and balanced against one another, in an attempt to tell the specific story in the form of a sequence of events that led to a patient's death. The pathologist can, but does not always, list an immediate cause of death, which is considered to be the one lesion without which death would not have occurred, as well as an underlying cause of death. The underlying cause of death is the specific disease or injury that started the course of events that led to the immediate cause of death. In addition, the pathologist may report other conditions that pre-existed or co-existed and contributed to the patient's death, but did not result in the death. (In a death certificate, there is usually a list, which starts with the most recent condition and then goes back sequentially in time, with each earlier condition causing the later condition.)

The pathologist may not always be able to give an immediate cause of death and may express some degree of uncertainty by the use of words such as 'presumed' or 'probable'. Like many other aspects of medicine, cause of death is, in essence, a concept or opinion based on all available information. As such, this opinion may be subject to differences in interpretation.

During 1994, the Chief Medical Examiner maintained a process to assist his office in determining if and when to order an inquest. Following a medical examiner's investigation the case could be referred to the Children's Inquest Review Committee. This committee included representation from the police, the Justice Department, the College of Physicians and Surgeons and family service agencies, and met approximately eight times a year. The committee advised the CME as to whether or not an inquest should be called, although the CME could order an inquest without the committee's input. Inquests were called when, in the public interest, it appeared that there were preventable aspects to a death and if the CME perceived a trend in deaths in a particular hospital or industry. Inquests were also called to allay public concerns and make known the circumstances surrounding a death.

BUDGETING

The three major sources of income for a hospital are government grants, revenue from medical services provided on a fee-for-service basis and donations.

The Department of Health provides grants to medical institutions on an annual basis, although sometimes grants are committed over a period of time. Negotiations occur between the hospital and the Province for those annual grants.

The Department of Health and the HSC had an arrangement whereby the Province provided an annual grant to the HSC that allowed the HSC to decide how to divide the money among its various departments. This was called global budgeting.

Under global budgeting, the various HSC departments negotiated with hospital administrators and committees for a share of the money. As with any such process, decisions were made in a manner that some saw as unfair. Those involved in pediatrics often felt that the lion's share of funding at the HSC was given to the adult side, leaving pediatrics with less than its fair share. This situation was said to arise because of the inordinate influence that those on the adult side seemed to have over the process of the distribution of money.

One would also have to recognize that the amount of money spent on services to adult patients would tend to reflect the fact that the numbers of adult patients at the HSC greatly outnumbered the pediatric cases. Additionally, adult patients provided a greater source of income from fees for service than did pediatric patients. This was not only because of the greater number of adults but also because the fee schedule, the basis for payment for those services, seemed to pay more for adult procedures than it did for those involving children.

It is difficult to describe with any degree of certainty the extent to which this tension between the adult and pediatric communities within the hospital might have played a role in the events surrounding the Pediatric Cardiac Surgery Program at Children's Hospital in 1994. Nonetheless, where it has been raised or may possibly have been an issue, mention will be made in this report.

THE RELATIONSHIP BETWEEN THE HSC AND THE FACULTY OF MEDICINE

The HSC is a teaching hospital. It maintains a close working relationship with the Faculty of Medicine of the University of Manitoba. Students in the Faculty of Medicine receive a portion of their training on the wards in the hospital. The Faculty of Medicine, in fact, is located next to the HSC.

Many of the hospital's senior medical staff also held positions in the faculty as assistant, associate or full professors, so that they could assume academic responsibility for the education of medical students within the hospital. While such medical staff might have been called upon to provide classroom instruction, much of the teaching that went on at the HSC occurred on the wards. Staff with dual appointments were paid for their medical duties by or through the hospital and received a small stipend for their educational duties from the University.

The hospital's bylaws and policies designated which positions were considered dual (i.e., requiring both a hospital and a faculty appointment). For such positions, both the university and the hospital had to approve the candidate's appointment. For the most part, the heads of medical departments and medical sections in the hospital held dual appointments, including the heads of the departments of Anaesthesia, Pathology, Pediatrics and Surgery.

Heads of the sections of pediatric surgery, cardiothoracic surgery, and pediatric anaesthesia were also dual appointees. Individual medical staff may also have had dual designations. In these proceedings, some of the pediatric anaesthetists and the pediatric cardiac surgeon involved in the deaths under review held dual appointments.

Section 2

Chapter 5

Pediatric Cardiac Surgery in Winnipeg 1950–1993

Introduction

Pediatric cardiac surgery is a relatively recent area of specialty, and pediatric cardiac surgery in Winnipeg generally mirrors its development in other parts of Canada.

The start of pediatric cardiac surgery at the Children's Hospital— the Ferguson-Cumming Era: 1950s-1981

Dr. Colin Ferguson, the first pediatric cardiac surgeon to operate in Winnipeg, began operating on children with heart problems in Winnipeg in the 1950s. This was at the time when the field of pediatric cardiac surgery was beginning to be recognized as a specialty separate and apart from adult cardiac surgery.

Coincident with Ferguson's career in Winnipeg, Dr. Gordon Cumming, a pediatric cardiologist, practised at the Children's Hospital. Together, Ferguson and Cumming provided Manitoba's first pediatric cardiac service. Before his retirement in 1978, Ferguson began to reduce the number of operations he was performing. After Ferguson's retirement, Dr. Jary Barwinsky, an adult cardiac surgeon at St. Boniface General Hospital, performed minor heart operations on children. Barwinsky generally restricted his operations to older, larger children and did not perform surgery on neonates. For that reason, Cumming, who was the only pediatric cardiologist in the city, referred such patients to pediatric cardiac surgery programs in other provinces.

Pediatric cardiac surgery was re-instituted at the Children's Hospital when Dr. Alberto de la Rocha was appointed to a position in the Department of Surgery at the HSC in 1978. By the fall of 1979, however, it was apparent that de la Rocha's success rate at pediatric cardiac surgery was mixed at best. Cumming lost confidence in both de la Rocha and the program, concluding that there were not enough cases in Manitoba to allow the surgeon to maintain an appropriate level of skill. As a result, Cumming stopped referring any of his patients to de la Rocha for surgery.

From 1979 onward, Cumming sent those patients who needed surgery to cardiac surgery programs in other provinces. De la Rocha continued to operate on children referred to him by other medical practitioners, but his caseload of pediatric cases never rose above a few dozen in any given year, with fewer than twenty open-heart procedures being part of this caseload.

The Ferguson-Cumming era ended in 1981, when Cumming retired from full-time staff at the Children's Hospital. By that time, very little pediatric cardiac surgery was being done in Winnipeg. The Health Sciences Centre chose to recruit a new cardiologist who had a vision of a much more expanded program.

THE COLLINS ERA: 1982–1993

In 1982 Dr. George Collins became the section head of pediatric cardiology at the HSC. Collins was also given the mandate to develop what came to be known as the Variety Children's Heart Centre (VCHC) and served as the VCHC's first medical director.

COLLINS'S BACKGROUND AND VISION

Collins had undergone his medical training in Scotland, attending medical school at Edinburgh University from 1951 to 1957, and then doing his residency there in both pediatrics and cardiology. He completed his postgraduate training at the Toronto Hospital for Sick Children in 1964.

From 1966 to 1968, Collins practised pediatric cardiology at the Toronto Hospital for Sick Children as a staff member. He joined the staff at McGill University Medical School in 1968. However, he spent much of the following 13 years in Kenya, as part of a Canadian International Development Agency program to establish a medical school in that country. During that period, he spent two years in the pediatrics department in Nairobi.

In 1981 he became the director of the heart catheterization laboratory at McGill University's Children's Hospital. He continued to practise pediatric cardiology and served as an associate professor of pediatrics. He directed the residency-training program, chaired the McGill Undergraduate Education Committee and was also quite involved in research activities.

The Winnipeg Health Sciences Centre recruited Collins in 1981. For the first six months of 1982 he worked part-time in Montreal and part-time in Winnipeg, taking on full-time duties in Winnipeg in the summer of 1982. Collins accepted the position because, in Manitoba, he saw an opportunity to put into action some of his thoughts and views on the delivery of pediatric cardiac services.

Before Collins agreed to take the position in Winnipeg, he and representatives of the hospital, as well as Winnipeg's medical community, discussed in detail whether or not a major commitment would be made to a complete pediatric cardiac surgical program. From the outset, Collins indicated that he was interested in coming to Winnipeg only if such a commitment existed. He felt that such a program would require a considerable amount of financial and moral support. He came to Winnipeg because he felt that such support was present, particularly after meeting with the President of the Health Sciences Centre, Peter Swerhone.

Collins's experience at both McGill Children's Hospital and the Toronto Hospital for Sick Children had convinced him that children who were referred from other programs or communities for cardiac surgery did not get the same care and attention as regular patients who received ongoing treatment from a local program. He felt that parents who arrived the night before surgery without any family support rarely received the briefing, education and attention that family members of local patients received.

He was also concerned about a distant program's inability to provide appropriate patient follow-up. He recalled that, in the early days of his involvement with Toronto's and McGill's pediatric cardiac services, a considerable amount of palliative surgery was undertaken, and many out-of-town patients never returned for a definitive repair, as would have been the case with a local patient.

Collins believed that a full-service program was needed to attract the best intensive-care and operating-room nurses, the best cardiologists and the best surgeons. He believed a surgeon was an essential part of any pediatric cardiac program. Without the presence of a pediatric cardiac surgeon, for example, pediatric cardiologists are unable to undertake any invasive cardiology—a growing and necessary field of treatment.

Collins felt the answer lay in the development of smaller pediatric cardiac surgery programs. The major programs in Canada at the time were in Toronto and Montreal, but Halifax, Edmonton and Vancouver were developing smaller programs. Collins came to Winnipeg because he believed that the evolution of pediatric cardiac services in Canada called for the development of such a service in this province.

Collins's ambitions for the program were high. His view was that Winnipeg could and should have a complete pediatric cardiac surgical program, capable of looking after the needs of children not only from Manitoba, but also from nearby provinces. He also had ambitions to provide cardiac services for children from Third World countries.

RELATIONS BETWEEN HSC AND ST. BONIFACE

Collins's timing could not have been better. He assumed the position at a time when efforts were being made to rationalize cardiac services in Winnipeg. To that point, the two major hospitals in the city, St. Boniface General Hospital (SBGH) and the Health Sciences Centre (HSC), had each been vying to be the main centre for cardiac services in the province, particularly in the field of adult cardiac surgery.

By 1981 most adult cardiac surgery was being carried out at SBGH. The small amount of pediatric cardiac surgery that was being done was performed at both SBGH and the Children's Hospital. The competition between the two hospitals had been seen for some time as unhealthy, in that it contributed to professional antagonism, to a duplication of services and costs, and confusion among members of the medical profession and the public. A number of studies and reviews had, in fact, recommended that cardiac services be centred at one or the other of the two major hospitals. While much of the discussion concerned adult cardiac services, the field of pediatric cardiac surgery called for the same considerations in Collins's eyes.

Before he actually started working in Winnipeg, Collins spoke with Dr. Morley Cohen, the director of the adult cardiac surgery unit at SBGH, and gained his support for his plan to establish a pediatric cardiac surgery unit at the Children's Hospital. After his discussions with Cohen, Collins believed that SBGH was going to be the centre for adult cardiac surgery in the province, while the HSC would be the centre for pediatric cardiac surgery.

By the time Collins started, however, the HSC had hired Dr. Jim Parrott, who became the acting head of the cardiovascular and thoracic section at the HSC and also performed adult cardiac surgery. In Collins's view this development flew in the face of what he had understood was going to occur. The hiring of Parrott continued the ongoing tension between medical staff of the two hospitals, a point that was mentioned frequently throughout the Inquest hearings.

THE PROVINCIAL ADVISORY COMMITTEE ON CARDIAC SERVICES IN MANITOBA

On February 15, 1982, the Minister of Health for Manitoba, Larry Desjardins, appointed an Advisory Committee under the chairmanship of T. A. J. Cunnings of the Manitoba Health Services Commission (MHSC) to advise the Department on the establishment of a provincial cardiac service program. Departmental officials had long been aware that the delivery of cardiac services was driven by competition between the HSC and SBGH. The Cunnings Committee had representation from the HSC and SBGH, as well as from the Department of Health. A part of the Committee mandate was a requirement to advise the Minister on how cardiac services in Manitoba should best be developed, including how best to use the resources of the HSC and SBGH.

In July 1982, Collins submitted a proposal to the MHSC for the establishment of a centre for pediatric cardiology services at the HSC. This centre was eventually to become the Variety Children's Heart Centre. The report was the result of Collins's close work with the heads of other medical departments and of his briefings and training sessions with nursing staff. The proposal only addressed the development of a specialized pediatric cardiology service, and was silent on the question of pediatric cardiac surgical services. Collins apparently took the position that the delivery of surgical services was the responsibility of the HSC's Department of Surgery.

In its report of August 1982, the Provincial Advisory Committee recommended an integrated approach with respect to both adult and pediatric cardiac surgery. It recommended that St. Boniface General Hospital be the primary adult surgical centre, while pediatric cardiac services were to be centred at the Health Sciences Centre.

In the spring of 1983, the provincial cabinet approved a modified plan whereby SBGH and the HSC would share the adult cardiac surgery workload, while pediatric cardiac services would be established exclusively at the HSC's Children's Hospital. It was specifically recognized that the number of pediatric cardiac cases would not justify having pediatric cardiac surgery at more than one centre, while the adult caseload seemed to be of sufficient numbers to justify splitting them between the two hospitals.

The decision to locate all of the pediatric cases at the Children's Hospital was welcomed by that hospital's Department of Pediatrics and Child Health as support for its view that the Children's Hospital should become the major centre for child health in the province. It also reinforced Collins's overall plan for the development of the program he had been hired to establish. The fact that the HSC was able to acquire a share of the adult caseload was also seen as a major development, especially since the bulk of adult cardiac cases had been performed at St. Boniface previously.

The province's decision to establish the HSC as the centre for the Pediatric Cardiac Surgery Program was accompanied by a significant financial commitment and an assurance that the province would not condone competition for pediatric cardiac cases. This latter assurance was, however, almost unnecessary since the number of pediatric cases was so small and so financially unrewarding as to be almost unattractive to other hospitals.

THE ESTABLISHMENT OF THE VARIETY CHILDREN'S HEART CENTRE

The Variety Children's Heart Centre was the vehicle by which the HSC intended to deliver its pediatric cardiac services to the children of Manitoba. The funding for the centre came from both the public and private sector, with the Variety Club making an initial contribution of $150,000 towards the renovations necessary to establish the centre and a ten-year commitment of $100,000 annually. All staff who worked within the centre were employees or staff of the HSC (and not the VCHC). Medical staff assigned to the VCHC were considered staff of the hospital in the same way as other hospital medical staff were. The Variety Children's Heart Centre name appears, therefore, to have been largely a public relations and administrative vehicle by which the HSC promoted its pediatric cardiac program. The VCHC was not a stand-alone agency.

Collins, for example, had little control over the centre's budget, which was administered by the Department of Pediatrics. In the end, according to Collins, "there was no such thing as a budget." (Evidence page 33,055)

Collins did, however, play a considerable role in creating the centre's culture. He saw nurses as having a key role in the operation of the centre, particularly in terms of relations with parents. While Collins was the centre's director and the pediatric cardiac surgeon was the deputy director, when the two of them were absent, a nurse, Lois Hawkins, served as the administrator.

Collins also attempted to ensure that the centre operated collaboratively. While the decision to operate always rested with the surgeon, he ensured that at least two cardiologists, as well as the surgeon, reviewed cases before they went to surgery.

COLLINS AND DE LA ROCHA

Collins had to determine whether or not he would continue to refer patients to de la Rocha, who was still operating at the HSC at the time of his arrival. Collins was aware of concerns with the poor surgical results in the operations in which de la Rocha had been involved and that Cumming was no longer referring patients to de la Rocha for surgery. After meeting with de la Rocha, Collins decided to refer patients to him. However, he restricted his referrals to de la Rocha to older children, sending his neonatal patients to Toronto's Hospital for Sick Children. Collins also urged de la Rocha to refrain from taking on difficult cases.

Collins felt from the outset that one of the reasons for Cumming's lack of confidence in de la Rocha and for the poor results was that de la Rocha did not exercise sufficient judgment in case selection. Rather, he allowed himself to be prevailed upon to try to perform miracles in hopeless cases. As a result, Collins felt that the reputation of the entire program of pediatric cardiac surgery at the Children's Hospital was suffering.

Collins had also felt that he and de la Rocha had developed an understanding as to which cases de la Rocha was to accept and how he was to handle patients referred to him by other doctors. However, de la Rocha was a member of the Department of Surgery at the HSC and was not accountable to Collins for the work he took on. In the fall of 1983 Collins came to the conclusion that de la Rocha was continuing to perform cardiac surgery on children who were not appropriate for such operations, and that he was also not enjoying particularly good results with those cases. The issue came to a head when Collins was called to the operating room after the start of an operation on one of his patients. This is how Collins described the scene.

> ... the whole team was disorganized. The pump wasn't working, there was too much blood in the heart, they couldn't see things, he was trying to repair a valve. And it was just a very disorganized event. (Evidence, page 32,955)

The next day Collins met with Dr. J. Haworth, the head of pediatrics (who was also head of the Children's Hospital), and Dr. Allan Downs, head of surgery, to discuss his concerns. Later that day he met with de la Rocha and told him that the next patient was going to be sent to Toronto. He then told de la Rocha that he was not going to refer any more patients to him and that he did not want de la Rocha operating on any more children with heart disease at the Children's Hospital.

This effectively ended de la Rocha's career as a pediatric cardiac surgeon in Winnipeg. Although he continued to perform adult cardiac surgery for several months in Winnipeg, he left the city the next year.

The program's poor results were reported in the media at the time. The program's future was at risk, particularly since Cumming had told the media that he did not believe that Manitoba had the population to support a full-scale Pediatric Cardiac Surgery Program (Exhibit 216).

Following his decision to stop referring patients to de la Rocha, Collins spoke with Barwinsky, who by that time was the chairman of the newly established provincial pediatric cardiac services program. He and Barwinsky developed a plan to reinstate pediatric cardiac surgery at the Children's Hospital, using Barwinsky's surgical services. Barwinsky had continued to perform simpler cardiac procedures at SBGH on older children, even after de la Rocha's arrival. As head of the Pediatric Cardiac Services Program, Barwinsky was aware of the plan to develop the program at the Children's Hospital as a full-service program.

After several months of planning and preparation, Barwinsky started performing pediatric cardiac surgery at the HSC in the spring of 1984. Collins and Barwinsky made a point of slowly restarting the program. This involved having preparatory meetings with the staff involved in the operations, including the nurses, and identifying their concerns. Collins also worked on establishing procedures governing how patients would be referred for surgery. Eventually a protocol was put into place that any medical referral for pediatric cardiac surgery from anywhere in Manitoba was to be made to the Variety Children's Heart Centre.

Barwinsky performed approximately thirty pediatric cardiac operations each year for a three-year period. However, Collins felt that it was essential to seek a surgeon who had been specially trained in pediatric cardiac surgery for the program.

RECRUITMENT OF DR. KIM DUNCAN

While Collins had always envisioned surgery as a major component in the pediatric cardiac program at the HSC, he had not anticipated the problems experienced with de la Rocha. However, with Barwinsky's support, he developed a plan for submission to the MHSC. In a document dated March 20, 1984, Collins set out his plan for the reintroduction of pediatric cardiac surgery in Winnipeg (Exhibit 17, Document 4). The plan, of necessity, included the hiring of a new surgeon.

While Barwinsky provided surgical services for the pediatric cardiac program during the initial period of the program's reintroduction, it was never intended that he would be the surgeon on a permanent basis. As the head of cardiovascular and thoracic surgery for the University of Manitoba Faculty of Medicine, Barwinsky took on the formal responsibility for hiring the new surgeon. According to Collins, it took the HSC eighteen months to find a suitable surgical candidate who was willing to come to Winnipeg. The choice was Dr. Kim Duncan, a young Canadian doctor (and the son of a doctor well known to Collins), who was still in training.

In the fall of 1985, Barwinsky met with Duncan in London, England, where Duncan was studying. Collins was intimately involved in the recruiting process; he was consulted on each applicant and held an informal veto over the appointment. The decision to appoint Duncan to the position of pediatric cardiac surgeon at the HSC was made in the fall of 1985. Duncan took up his duties in the summer of 1986.

Duncan had undertaken his medical training at the University of Alberta, where he graduated with his medical degree in 1976. He interned in Ottawa and did his residency in general surgery at the University of Alberta from 1977 to 1982. From 1983 to 1985 he did a residency in cardiovascular and thoracic surgery at the University of Alberta Hospital and at the Royal Alexandra Hospital (both in Edmonton). He was the Chief Resident at the latter hospital for six months. He was the senior registrar at the Great Ormond Street Hospital for Sick Children in London, England for one year during that time as well. (A senior registrar at an English hospital is equivalent in Canada to a Fellow—a doctor who is past the residency stage of training but does not yet have a staff appointment and is undergoing more training.) From July 1985 to July 1986, he was a clinical assistant professor of cardiovascular surgery at the Toronto Hospital for Sick Children.

When Duncan came to Winnipeg, he was appointed the director of surgery at the VCHC. Collins testified that, by appointing his staff as directors of one sort or another, he was able to pay them more.

Collins's plan for the Variety Children's Heart Centre called for the appointment of three cardiologists. By 1986, Dr. Robert Vincent, Dr. Andrew Pelech and Dr. Niels Giddins had been appointed to the cardiology staff of the centre. Vincent subsequently left to practise in Toronto and was replaced by Dr. Brian McCrindle.

THE MATRIX CONCEPT

The VCHC was what was referred to informally at the HSC as a matrix. Within the administration of the hospital, a matrix was a program that brought together a number of disciplines and services—in this case, cardiology, surgery and nursing. However, what was not very clear when it came to a matrix was how the lines of authority and responsibility worked, and the degree to which necessary alterations to the usual lines needed to be made to accommodate the matrix.

During the course of evidence, differing explanations were given as to the lines of responsibility at the VCHC. At times, witnesses, who should have been clear as to the lines of responsibility and authority, said they found the lines to be confusing.

For example, when asked who his 'boss' was, Duncan identified Collins in day-to-day matters, but said that in official terms it was Barwinsky and Dr. Robert Blanchard, the chief of surgery. Duncan then added that one might also consider the chief of the pediatric surgery division, then Dr. Mervin Letts, as his "immediate boss." (Evidence, page 23,412)

Collins told the Inquest:

> Kim Duncan was the director of the surgical program. He reported to Bob Blanchard, or when there was a division head of cardiac surgery like Jary Barwinsky, or later on Helmut Unruh, he reported through him to Blanchard. (Evidence, page 32,993)

Dr. Helmut Unruh who was the acting chief of CVT surgery from 1991 until January 1995, said:

> I did not have any direct responsibility for the day to day activities of Dr. Duncan or any other cardiac surgeon at the Children's Hospital. (Evidence, page 34,958)

When asked what, if any responsibility he had had for the pediatric cardiac surgery program, Unruh said:

> *A.* I had none.
>
> *Q.* You had none?
>
> *A.* No.
>
> *Q.* Okay. When Dr. Duncan was here, who did have responsibility for the pediatric surgery program and/or Dr. Duncan's clinical activity in that program?
>
> *A.* The director of the pediatric cardiac program, Dr. George Collins. (Evidence, page 34,959)

Unruh suggested the situation was similar to the HSC having placed Duncan in another hospital on a secondment. In such a situation, he pointed out, it would be up to that institution to monitor the surgeon's medical practice.

During the Collins era, however, such confusion over lines of authority did not create any significant problems, since Collins himself played a significant role in monitoring the program's performance and surgical results. However, this issue was a recurring matter during 1994.

THE RELATIONSHIP BETWEEN COLLINS AND DUNCAN

The controversy that had been generated by de la Rocha's experiences shaped the relationship between Collins and Duncan on the latter's arrival in Winnipeg. Duncan testified that after he arrived in Winnipeg, he was often told that there must not be a duplication of the de la Rocha experience. When asked what he understood the de la Rocha experience to be, he testified:

> They had what people felt was unacceptable mortality, unacceptable conduct, unacceptable patient management. They emphasized the mortality, but the mortality by itself wasn't what I think really

> upset people the most. It was the lack of, the lack of ability of the individuals involved to communicate and to work together. (Evidence, pages 23,478–23,479)

Collins and Barwinsky worked together to ease Duncan into surgery in Manitoba. The two men arranged the surgical schedule to ensure that Duncan's first Winnipeg operations were on older children. Barwinsky made a point of assisting at Duncan's first operations. This attitude is reinforced by a letter from Collins to Dr. Agnes Bishop, the head of pediatrics and child health at the HSC, on March 6, 1986, in which he wrote:

> However, this year Kim Duncan arrives in early July. While the start will be very gradual, there would be a real advantage to having him get used to the team by doing one operation a week working with Jary Barwinsky on simple cases, much like we are doing at present. (Exhibit 17, Document 44)

Although he had arrived in the summer, it was not until December 1986 that Duncan actually operated on an infant in Winnipeg. The operation was not a planned procedure. It took place because a plane en route from Sault Ste. Marie to Toronto, and carrying a child in need of an emergency operation, was diverted by a storm to Winnipeg. The operation went well.

Collins made it clear that he did not want the surgical program to take on more than it could handle. Duncan said:

> He told me that he wanted to be able to do virtually everything in Winnipeg, every kind of case. And he said that he needed me to tell him when I was ready, or when I felt our team was ready, and when I felt that we needed to go slow or not do a case. And he also said that if he saw things happening that he would intervene and say, we should think about something else. (Evidence, page 23,347)

Collins was also concerned that Duncan not undertake surgery when he was in less than optimal condition. He once dissuaded Duncan from performing surgery one morning when Duncan had been up all night attending to a child in the intensive care unit. While Collins was concerned about the program's reputation, it is clear that his overriding concern was the patients' safety and well-being.

COLLINS'S ROLE IN MONITORING PERFORMANCE

Concepts of quality assurance and continuous improvement were relatively new to the Canadian health-care system in the mid-1980s. Much of the VCHC's records were kept on cards, as opposed to computers, making it very difficult to develop the type of database that a quality assurance program requires.

While Collins worked to establish a more sophisticated statistical database, he also worked at informal methods of quality assurance. Collins testified:

> quite honestly talking to Kim Duncan over a cup of coffee is quality assurance too. In other words, it is happening every day when we are together. (Evidence, page 33,095)

Collins also made sure that the team dealt with negative outcomes as a team. As he described it, following what he called "bad patches", "We drank more coffee, we stayed later, we talked as a team." (Evidence, pages 33,135–33,136)

In addition to this, Collins made sure that the centre conducted annual reviews of its work.

THE VCHC'S CASELOAD

With the arrival of Duncan, the number of children who were being referred out of province began to decline dramatically. By 1987 the VCHC's patient volume was double what it had been in 1984. This increase levelled off by 1988, which was seen by Collins as an indication that the centre was treating all Manitoba children with heart conditions. By 1988, the Manitoba government required that no child could be sent out of province for heart surgery unless Collins had stated the operation could not be done in Manitoba.

There were times, however, when the pediatric cardiac surgical program did slow down. After experiencing poor results with a number of Norwood operations, the approach was to encourage parents to consider comfort care as opposed to having their children undergo the high-risk Norwood.

In addition, Collins had always hoped to see the program expand its outreach to patients from Northwestern Ontario, North Dakota and even the Third World. After the program had been in place for a decade, 12 per cent of its patient caseload came from out of province.

By 1993 the VCHC had, besides Collins, three academic pediatric cardiology positions, four cardiovascular technologist positions, three nurse-clinician positions, three secretarial positions and one database manager/computer consultant. However, from 1990 onwards, the program was hit with ongoing funding cuts that affected all of the HSC. It proved to be difficult to keep all these positions filled.

ISSUES FOR THE VARIETY HEART CENTRE

There were a number of ongoing issues that Collins attempted to have addressed, during his tenure as director of the Variety Children's Heart Centre.

Operating rooms

The operating room that was used for pediatric cardiac surgery had space, ventilation and temperature-control problems. While improvements were made, the state of the operating room was never deemed to be satisfactory. Despite the improvements, Theatre 2 was judged to be small by witnesses who appeared before this Inquest. The theatre was cramped because of all the specialized operating room equipment required, such as the perfusion pumps, and the greater number of team members necessary. In addition, problems with temperature control frequently led to fluctuating operating room temperatures. This made it more difficult to control a patient's temperature, always a critical issue in pediatric anaesthesia.

The VCHC offices

Pediatric cardiology had originally been housed in the basement of the Children's Hospital, and much of its equipment dated back to the early 1960s. The VCHC was eventually housed on the main floor of the HSC's Community Services Building, which is across William Avenue from the Children's Hospital building. By the time Collins left, he testified, the VCHC was the best-equipped centre in the country.

However, the state of medical technology was always evolving, particularly in the field of cardiac services. In order to maintain its status as a state-of-the-art facility, it was important for the centre to be able to make regular equipment and technological purchases. This was a constant challenge for the centre.

The medical fee schedule

Medical fees paid to physicians in Manitoba are paid in accordance with a fee schedule negotiated from time to time by the Manitoba Medical Association (MMA) and the Province of Manitoba.

The MMA fee schedule in place during Duncan's and Collins's tenure did not, in their opinion, reflect the development of the specialty of pediatric cardiac surgery. When the fee schedule had originally been set, pediatric cardiac surgery was a limited field, particularly when compared with adult cardiac surgery. As a result, fees paid to surgeons for pediatric cardiac procedures were generally lower than were those for adult procedures.

Additionally, even where the fees for each procedure were comparable, because the number of pediatric cases in Manitoba was considerably lower than the number of adult cases an adult surgeon could perform, the potential income for a pediatric cardiac surgical specialist was far lower than that for an adult surgical specialist. Duncan made far less money performing a pediatric cardiac operation of considerable complexity than he did for assisting at a simpler adult procedure for which he had no post-operative responsibility. The lack of resolution of this issue eventually contributed to Duncan's decision to leave Manitoba in 1993.

Relations with adult surgery and the hospital administration

Because he was the only pediatric cardiac surgeon in the city (other than Barwinsky, who still did not perform any cases of complexity nor cases involving neonates), Duncan not only did all of the cardiac procedures, but also all of the follow-up care required of a surgeon.

The evidence also established that Duncan not only provided the post-surgical care that was normally expected of a surgeon, but also took special interest in his cardiac patients. He often spent the night in the intensive care unit at the bedside of his patients, after he had spent the previous day in the operating room performing surgery on them. This was the case even when a child spent several days recovering.

Collins believed that, because the adult cardiac surgery program was much larger than the Pediatric Cardiac Surgery Program, the concerns of the pediatric program tended to be ignored. For example, Duncan provided coverage services for adult cardiac surgery, while adult cardiac surgery did not provide a similar service for pediatric cases. When Parrott left the hospital in 1991, Duncan was called upon to carry an adult caseload, as well as his regular pediatric cases. As a result Duncan found himself on call—for literally 24 hours a day, seven days a week—for two different programs.

Duncan, in particular, believed that the pediatric cardiac program was largely ignored by both the university and the hospital administration.

This issue was part of a broader conflict between the HSC's adult and pediatric services. One of the steps taken to address this was the creation of the position of head of pediatric surgery. Dr. Mervin Letts initially held this position during this period and was replaced by Dr. Nathan Wiseman. As head of pediatric surgery, Letts served as head of a committee of pediatric surgeons. The purpose of the creation of this committee was to provide a voice to allow pediatric surgeons more input into the institution.

Assistance for Duncan

Duncan, as noted above, was under considerable pressure. His status as the sole pediatric cardiac surgeon in Winnipeg and the lack of a local pediatric cardiac training program often left him in the position of not having the same surgeon assist him from case to case.

The importance of the surgical assistant was made clear to the Inquest by Dr. Garry Cornel[1], a consulting witness to this Inquest. He said:

> I think familiarity is perhaps the most important requirement, so getting used to somebody and working together is tremendously valuable. At times in the past, in Newfoundland, I had to work with different assistants very often, and I found that very unsatisfactory, and was able to recruit a full time assistant.
>
> In Ottawa now we have a residency training program, so there is a senior cardiac surgery resident present for all cases, and often there are two staff people for each case as well. If it is an unusual case that I especially want Dr. Weerasena to familiarize himself with, one or other of us will be first assistant, depending on who is actually doing the surgery, and the resident will be there as the second assistant. At other times I will have the resident assist Dr. Weerasena, and I may stand and look over his shoulder, and vice versa. (Evidence, pages 44,631–44,632)

Cornel added that being a trained cardiac surgeon was a significant factor in an assistant:

> In a complex case, and especially if things have gone wrong, somebody with experience may provide an idea of another way to try, or another way to do things, and that can be of great help.
>
> The assistant that I have had for the past ten years in Newfoundland is still there, we still work together, and it is a wonderfully satisfactory arrangement. He is just a marvellous assistant, he knows what I am going to do before I even think about it, and so that's equally satisfactory. But we—you know, for a new very complex case, I would prefer to have Dr. Weerasena to help me. (Evidence, page 44,633)

The HSC was seeking an adult cardiac surgeon who could also assist in pediatric cardiac surgery. However, it was not able to recruit such a surgeon during Duncan's tenure. For Duncan, this became a source of some frustration. A partial solution was formulated when Dr. B. J. Hancock, who had been one of Duncan's most consistent assistants, decided to seek specialty training as a pediatric general surgeon and intensivist. She left for her training with the thought in mind that she would eventually return to Winnipeg, in part to be a pediatric cardiac surgical assistant, in addition to becoming a pediatric general surgeon.

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[1] Dr. Garry Cornel is an associate professor of surgery at the University of Ottawa and director of the division of cardiovascular surgery at Children's Hospital of Eastern Ontario in Ottawa.

Born in England, Cornel graduated from the University of London and was certified in cardiovascular and thoracic surgery in 1974.

He trained in the Department of Cardiology at the London Hospital in 1963 and in pediatric surgery at Birmingham Children's Hospital in 1964. From 1969 to 1971, he was an associate resident and then chief resident in general surgery at Buffalo General Hospital and from 1973 to 1974 was the chief resident in CVT surgery at the University of Alberta. He was licensed to practice cardiovascular surgery by the College of Physicians and Surgeons of Ontario, as well as the Newfoundland Medical Board.

In 1991, he was appointed chief of the division of cardiovascular surgery at Children's Hospital of Eastern Ontario, as well as associate professor of surgery at the University of Ottawa. As well, in 1991, he was appointed as a consulting staff member of the Janeway Child Health Centre in St. John's, Newfoundland with full privileges in cardiovascular surgery.

Cornel was acknowledged as having special expertise in pediatric cardiac surgery and was permitted to give opinion evidence with respect to pediatric cardiac surgical issues.

Lack of cases

Duncan's frustrations were expressed in a letter of July 28, 1989, to Bishop (Exhibit 17, Doc 92). In this letter Duncan complained that he was not performing enough pediatric cardiac operations to maintain and further develop his skills. After Parrott left in 1991, Duncan began performing adult operations, but there were difficulties in scheduling these operations.

The number of anaesthetists

According to Collins, the HSC had an embarrassment of riches when it came to pediatric anaesthetists, since there were six to seven qualified pediatric anaesthetists. The problem was that he felt there were not enough pediatric cardiac operations to allow them to maintain their skills. He testified:

> The problem in it all is when you come to open heart surgery and running pumps, it requires practice. And I don't know what pumps a year are, but maybe it is six pumps a month, and if you have got six anaesthetists, that's one pump each a month, and you are beginning to get into a situation where maintenance of skills can be questioned. (Evidence, page 33,079)

Duncan believed that there should be a limit on the number of anaesthetists who were involved in pediatric cardiac surgery. This was meant to ensure a high level of skills and teamwork. Duncan wrote of this "I cannot have a trusting relationship with individuals who I see only eight or ten times a year in the OR." (Evidence, page 23,601) This issue was never resolved before his departure.

Intensive care

Collins would have preferred to have all open-heart cases, no matter what their age, go to the PICU. Because there were more NICU nurses and neonatologists than there were PICU nurses and intensivists, he worried that the NICU staff did not have sufficient exposure to pediatric cardiac surgery cases. However, the neonatologists opposed this proposal. It also was not physically possible to send all the open-heart cases to the PICU in the early years of the program, since the PICU was smaller than the NICU and had older equipment. However, by 1993, the PICU had been upgraded substantially, having expanded into a larger space with newer equipment, to become a state-of-the-art facility. This issue of two intensive care units was also not resolved before Duncan's departure.

DEPARTURES

From 1990 onwards, a number of other hospitals had tried unsuccessfully to recruit Duncan. For his part, Collins had hoped that Duncan would take over from him as director of the program. However, by 1993 it was apparent that the program was in for major personnel changes.

By the summer of 1992 Dr. Brian McCrindle had left the Heart Centre. Due to a hiring freeze at the HSC, he was not replaced. When McCrindle had been hired, the other cardiologists at the Variety Children's Heart Centre had agreed to forgo income that would otherwise have been available to them, in order to pay his salary. With McCrindle's departure, the centre was left with three cardiologists to do the work that four had previously performed. The money that they had forgone in order to hire McCrindle was lost to them with the freeze. Matters, moreover, were to get worse.

In the spring of 1993, Dr. Andrew Pelech announced his intention to leave the Heart Centre and accept a medical position in Milwaukee. His resignation took effect in the fall of 1993.

In April 1993, Collins gave notice to pediatrics head Dr. Agnes Bishop of his intention to leave at the end of six months (Exhibit 291). Collins intended to leave Canada for a position as head of pediatrics at the King Fahad National Guard Hospital in Riyadh, Saudi Arabia. He testified that he had always planned to leave Winnipeg for other opportunities after ten years, and 1993 marked his tenth year in Winnipeg.

However, Collins's letter explaining his resignation (Exhibit 292) also spoke of his frustrations as medical director of the VCHC and with the manner in which the hospital and the Government of Manitoba were addressing issues related to pediatric cardiac surgery in the province.

In his letter of resignation, Collins questioned the commitment of both the HSC and the Government to provide the program with sufficient support for it to achieve its objectives. He also questioned the HSC's commitment to developing the program into the full level of service that he had always wanted. Collins's last day at the VCHC was October 31, 1993.

He was not alone in his frustration. By the end of April of 1993, Duncan had also decided to leave. He had discussed his decision privately with Collins on more than one occasion, and had also discussed his inclination to leave with some of his colleagues, including Unruh. He had turned down approaches from hospitals in London and Ottawa, but by April was being recruited by a hospital in Omaha, Nebraska.

Duncan and others testified that when he was being considered for the position that he ultimately accepted in Omaha, those who were recruiting him came to Winnipeg in order to watch and videotape him while he was actually performing a surgical procedure. The videotape was made to help the staff who were going to work with him observe and learn about him and his surgical technique.

The chief of surgery from Omaha also came to Winnipeg to observe Duncan performing surgery. According to Duncan, the chief surgeon later told him that, among other things, he wanted to observe Duncan's relationship with others in the operating room.

On May 10, 1993, Duncan gave Collins written notice of his intention to depart. He said that he would not accept any new patients after June 1993, and would stay until the end of July to finish those cases in which he was involved. That June, Duncan performed the final procedures for which he was responsible, and shortly thereafter departed for his new position in Omaha.

By November 1993, therefore, McCrindle, Pelech, Duncan and Collins were all gone. This meant that there was no surgeon and that Giddins was the only pediatric cardiologist on staff. On Collins's recommendation, Giddins was appointed the acting medical director of the Variety Children's Heart Centre. The cardiac surgery program that Collins had worked so hard to build had been virtually decimated by the end of 1993.

REPLACING DUNCAN

Dr. Helmut Unruh, as the acting head of cardiovascular and thoracic surgery at the HSC, played a central role in recruiting a replacement for Duncan.

Unruh had graduated in medicine from the University of Manitoba in 1977. He completed his residency in general surgery in Manitoba in June 1980 and trained in thoracic surgery for a year in England. From July 1984 to December 1984, he was a clinical fellow in cardiovascular and thoracic surgery at Montreal General Hospital, which was affiliated with McGill University. While at McGill, Unruh had worked with Dr. David Mulder, the chairman of that department, Dr. Tony Dobell, the department's program director, and Dr. Ray Chiu, the department's director of research.

Unruh's specialty was in thoracic surgery, as opposed to cardiac surgery. A thoracic surgeon's field of practice is limited to doing everything in the thoracic (or chest) cavity except cardiac surgery. While at one time thoracic surgeons had combined the specialties of cardiac and thoracic surgery, each field had evolved over time into separate specialties.

After finishing his training at McGill, Unruh returned to Manitoba in January 1985, and was appointed an associate staff member of the Department of Surgery at the HSC. He was concurrently appointed assistant professor in the Faculty of Medicine at the University of Manitoba. He became an active staff member of the Health Sciences Centre's Department of Surgery in 1988 and was the service chief of thoracic surgery from 1988 to 1995. In 1993, he also became a staff member of St. Boniface General Hospital, in its Department of Surgery.

In 1988, Unruh was appointed the acting section head of cardiovascular and thoracic surgery in the Faculty of Medicine. Following Parrott's departure, Unruh was appointed to a concurrent position as the acting section head of cardiovascular and thoracic surgery at the Health Sciences Centre. In the latter capacity, Unruh was responsible for the day-to-day management of the cardiovascular and thoracic section of the Department of Surgery at the HSC.

The search committee

Dr. Robert Blanchard, the head of surgery, believed that it would be difficult to attract a capable candidate for pediatric cardiac surgery to Winnipeg and it would be even more difficult to retain such a candidate. In a letter to Manitoba's Health Minister, Don Orchard, dated March 30, 1993, (Exhibit 25, Document 93/3), Blanchard wrote that Unruh was initiating contacts to see who might be available to be recruited as a replacement.

A meeting was held on April 19, 1993, between Collins, Blanchard, Unruh and Bishop, to discuss Duncan's replacement. According to the minutes (Exhibit 18, Document 233), the discussion focused on the savings that the province would realize by not having to send children out of province for treatment and by the general benefits that a pediatric cardiac surgeon provided to the HSC. If the HSC was to continue to evolve into a full-service tertiary-care hospital, it was thought that pediatric cardiac surgery should be offered to the public. For those reasons the group decided that Duncan should be replaced and the program should be maintained.

The minutes of that meeting stated that "Dr. Unruh was encouraged to continue his efforts to recruiting a pediatric heart surgeon." (Exhibit 18, Document 233) Since a pediatric cardiac surgeon would be appointed to the Department of Surgery, and to that department's cardiovascular and thoracic section, Blanchard and Unruh played the lead roles in identifying candidates.

The evidence provides differing interpretations of that recruiting process. Unruh said that there was a three-person committee, consisting of himself, Blanchard and Collins involved in the appointment of the new surgeon. He also said that Collins's role in the committee was pivotal, since he spent more time with the candidates than either Unruh or Blanchard.

Collins, on the other hand, testified that he was not part of the search committee, although he said that he was consulted about all the candidates and met with most of them. Unruh, Blanchard and Collins all agreed that no candidate would have been accepted without Collins's approval. Although Blanchard and Unruh communicated with each other by letter on the recruitment process, they generally did not provide Collins with copies of their correspondence. It would seem, therefore, that the process involved Unruh finding a suitable person, vetting the name with Blanchard, and seeking Collins's final approval. It would be less than accurate to say that a formal search committee was in place.

The recruiting followed both a formal and an informal process. Advertisements were taken out in various medical publications and Unruh began working his network of contacts in the world of cardiac surgery. By May 1993, he had come up with a list of potential candidates. According to Blanchard, Unruh was expected to do the initial interviews by himself and pass on those candidates who he believed should be considered.

During this period, Unruh had heard rumours that Collins was going to leave the HSC, but he did not believe them. Therefore, Unruh never told any of the people applying for the position of the significant changes that were taking place at the VCHC.

In late April or early May, Dr. Ray Chiu, one of Unruh's former colleagues at McGill, introduced him to a former student of his, who was looking for a position as a pediatric cardiac surgeon. The meeting took place in Chicago at a cardiovascular and thoracic surgical conference. The doctor Chiu was recommending was Dr. Jonah Odim.

Dr. Jonah Odim

Odim was a U.S.-trained doctor who had undergone a portion of his training in Canada. After graduating from Yale Medical School in 1981, he interned at the University of Chicago. From 1982 to 1987 he was a resident in general surgery at the University of Chicago. As a part of his training there, he participated in pediatric cardiac surgery. During his stay at Chicago he rose from the position of junior resident to senior resident, eventually becoming the chief resident in 1985. During the two years that he held this position, he was not extensively involved in cardiac surgery.

Following the completion of this residency, Odim could have gone into practice as a general surgeon. However, he had been attracted to cardio-thoracic surgery and sought additional training.

For this training he went to McGill University in Montreal, where he was a resident in cardiovascular and thoracic surgery from July 1987 to June 1989. His training at McGill followed a series of six-month rotations. From July 1987 to January 1988 he was in general thoracic surgery at Montreal General Hospital. In this position he often acted as the primary surgeon.

From January 1988 to July 1988 he was involved in pediatric cardiac surgery, also at the Montreal General. At that time Dr. Christo Tchervenkov was the dominant pediatric cardiac surgeon there, working under the tutelage of Dr. Tony Dobell, who was then on the verge of retirement. Dobell was training Tchervenkov to take over his position within the hospital.

During this period, Odim assisted at Tchervenkov's operations, usually as a first assistant. In simple cases, Tchervenkov allowed Odim to perform the operations with his assistance. As an assistant to Tchervenkov, Odim told the Inquest that he was responsible for getting patients into the operating room, putting in all of the lines, inserting the Foley catheter, prepping the patient, draping the patient, making the incision and starting to open the chest. He would assist with cannulation, although in some cases he completed the entire cannulation process. Odim estimated that at McGill there were approximately one hundred bypass cases a year. He also said that in his experience there were only two anaesthetists who worked on these cases.

From July 1988 to January 1989, Odim was Chief Executive Resident at Montreal General Hospital. For the following six months he was at Montreal's Royal Victoria Hospital where he did adult cardiac surgery. He stated that by the end of the rotation he was doing most of the cases with the assistance of the staff surgeon. However, because he was still in training, he was required to be under the supervision of a senior surgeon when performing surgery. Following this training he undertook the appropriate examinations of the Royal College of Physicians and Surgeons of Canada and qualified as a cardiac and thoracic surgeon in 1991.

At this point, Odim chose not to go into practice. Instead, he was encouraged by Chiu, who was also at McGill, to complete a three-year research project leading to a Ph.D. This research involved using skeletal muscle, as opposed to cardiac muscle, to rebuild and power failing hearts. This was intended to provide a treatment for people who were in the end stage of heart failure and had been turned down for heart transplants.

Odim explained that the decision to go into research was not unusual for someone who, as he did, intended to work in a teaching hospital setting. While the work with Chiu largely revolved around animal research, there were six patients whose treatment, as a part of the research project, required cardiac surgery. Odim was the first assistant in these operations. When asked if he worried about any erosion of his surgical skills during this three-year period, he said:

> I was doing a lot of bypass work in the animals, using the same techniques that I would be doing in the human operating room. So I wasn't, I was attending all of the conferences, I was making rounds. (Evidence, page 23,887)

In addition, he said, he assisted Chiu in a number of emergency operations.

Following the completion of this period of research in 1992, Odim decided to take further training in pediatric cardiac surgery. He was accepted as one of five residents at one of the world's leading centres for such surgery, Boston Children's Hospital, which is affiliated with Harvard University.

The residency at Boston Children's is broken down into two six-month periods: the first six months being clinical in nature, the second six months consisting of clinical research. The six months of clinical work is devoted almost exclusively to work in the operating room and intensive care. Working on a series of week-long rotations, one resident would work in the intensive care unit, while the other four worked as either first or second assistants in the operating room. At Boston Children's there were two operating rooms devoted to pediatric cardiac surgery, and a total of four operations would be performed every day. Two residents were assigned to each operating room. Each resident would serve as first assistant on one operation and second assistant on the other operation.

Odim gave the following description of the responsibilities of a first assistant:

> In general the responsibility was to get the patient in the operating room to start at 7:30 sharp. You put in the lines, cut down for an arterial line, you assisted the nurses with scrubbing the patients. And you began to open the chest and isolate the great vessels, prepare for cannulation. And usually around that juncture, depending on how efficient you were, the staff man would be entering the room, and once he was scrubbed up, he would come to his side of the table and you would switch and the case would proceed. (Evidence, pages 23,895–23,896)

He said the assistant would normally have accomplished the following steps by the time the surgeon arrived in the operating room.

> You would have opened the chest, opened the major skin incision, opened the sternum. You would have removed the thymus, which is a gland that cloaks the inlet of the chest cavity. You would have opened the pericardium, and you would have dissected out the great vessels. You might have put your purse strings in and you may have even begun to cannulate. (Evidence, page 23,896)

According to Odim, he had quite a bit of experience during this time with cannulation. He gave the following description of the work of the first assistant during the course of the operation.

> You have to guide the surgeon. You have to know the steps and be ahead of him so that you are prepared, which means spreading tissue, applying counter traction, so that the path way is open for him to see, tying sutures, cutting sutures, removing clamps, decannulating, all of those types of things are done by the first assistant. (Evidence, page 23,898)

In this passage, 'guiding' means anticipating the surgeon, not providing the surgeon with direction. Following the operation, the first assistant might carry out decannulation. Odim said that, for the most part, none of this was new to the residents. Instead they were "learning some of the nuances from some of the leaders in the field." (Evidence, page 23,901)

In certain situations, Odim performed a number of operations as the primary surgeon. These included what he called simple cases, such as repairing atrial septal defects. The attending surgeon would act as the assistant in these operations, but would always be in a position to take over from the resident if anything problematic occurred.

Odim described Boston Children's Hospital as being unique in terms of its manpower and resources. Most of the operations that were performed there were complex re-operations. There were only two to three anaesthetists who, as far as Odim could discern, did almost exclusively pediatric cardiac work. There was also a separate pediatric cardiac intensive care unit.

Recruitment

Odim was half way through this clinical rotation when Chiu introduced him to Unruh at the Chicago conference. The two men spoke about the Winnipeg program for over an hour. According to Unruh, for Odim the conversation would have felt like an interview. Unruh was impressed with Odim.

> He had an excellent deportment, presented himself very well, had a very impressive background, general surgery at the University of Chicago, cardiac surgery at McGill University, potential Ph.D. from that institution. And now he was at one of the foremost Children's Hospitals in the world, at Harvard. I was very impressed with him in terms of his preparation for the job and also in the way that he conducted himself during the interview. (Evidence, page 35,016)

Odim was at that point starting to look for a position as a pediatric cardiac surgeon and had job prospects in both Chicago and Buffalo, New York.

Blanchard believed that the HSC could recruit one of three types of surgeons for the pediatric cardiac post available at the Children's Hospital. One would be a surgeon who was looking to wind down his or her career, the second type would be a surgeon at the peak of his or her career and the third would be a new surgeon looking to start his or her career. He said that the first option would not be preferable for a teaching hospital, since a surgeon at this point in his or her career would not be sufficiently up to date. It was thought to be unreasonable to expect to recruit a surgeon at the peak of his or her career to a program in which the surgeon would operate on his or her own. It was believed that the best results would come from recruiting someone at the start of his or her career. Given the fact that the HSC was a teaching hospital, a new surgeon with a research background would be the first choice. Such a person, Blanchard said, would keep the HSC on the cutting edge.

Of the candidates that the HSC was interested in, one took a position with the University of British Columbia, while another candidate did not have the research background that Blanchard was looking for. As a result, the search began to focus on Odim.

Unruh said that he conceived his role in the recruiting process as that of a facilitator.

> Well, a lot of this was being spearheaded by Dr. Blanchard, the chairman of the department. My process was really to assist him, and he delegated certain activities to me. (Evidence, page 35,033)

As a part of the recruiting process, Odim was brought to Winnipeg in August 1993. The visit was to allow Odim to meet with the people involved in the VCHC program and allow them to assess him. During that first visit, Odim was introduced to many of the people involved in the treatment of children with heart disease, including operating-room nurses, intensive-care staff and anaesthetists. He also met with both Collins and Giddins.

Blanchard and Unruh both told the Inquest that they expected Collins to assess Odim's clinical skills. Unruh also expected that Giddins would play a role in assessing Odim's surgical skills, although Unruh also said he did not know how Collins and Giddins had gone about assessing Odim's surgical skills. Blanchard described his conception of his role in the recruiting process in the following terms:

> So that generally my role would be relating to the academic realm as the academic head because there are a lots of other people in the clinical realm that will be dealing with that, that would have closer touch with that.
>
> Consequently my concerns about research, teaching; and then my other role is to outline carefully and clearly and completely to the individual, you know, how the organization runs and what their role is in it and what the fiscal arrangements could be. I mean that's how it works and that's what this is. (Evidence, page 36,372)

Odim's name had come up in a conversation between Collins and Dobell before the recruiting process had started. However, Collins never contacted Dobell for an assessment of Odim's skills. Collins was familiar with Dobell, having worked with him at McGill.

> So I had good reason to believe that anyone who survived Tony Dobell's training program had been through a rigorous training. (Evidence, page 33,205)

Collins said he spent several hours with Odim during that first visit, and the two men had a meal at a Winnipeg restaurant. During their conversation, Collins never informed Odim that both he and Pelech would shortly be leaving the VCHC. (Pelech's replacement, Dr. Cameron Ward, was not expected to arrive until the summer of 1994.) Collins also spent a considerable amount of time with Odim when he returned for a visit in the fall.

Letters of reference

Unruh said that under the HSC's protocols, the process of obtaining and checking on references was Blanchard's responsibility, not his. As a result, he did not call Boston Children's Hospital to ask any questions about Odim's performance. Nor did Unruh ever see any of the letters of reference dealing with Odim.

Unruh said that, if he were hiring someone who would be directly responsible to him, he would contact the program director and ask how the person had performed in the residency. He thought this would be much more important than letters of reference. Unruh said he believed that Odim's clinical work in Boston was satisfactory because if it had not been, "his time there would have been cut short." (Evidence, page 37,643)

When Odim applied for the position with the HSC, he gave three references. They were from people who had been involved with Odim during his research at McGill. Blanchard and Unruh both said that they did not put as much value on letters of reference as on informal contacts with the authors of the letters. In some cases they believed a letter writer might be either overly cautious in describing a candidate's skills or overly generous. This, they felt, was less likely to happen in personal conversation.

Chiu sent Blanchard a strong reference for Odim on August 30, 1993.

> He is a competent and skillful clinical surgeon, and with additional training at Boston's Children's Hospital, I suspect that he has become a capable pediatric as well as adult cardiac surgeon. Thus, I believe that potentially he could be a strong addition to your excellent team. (Exhibit 45, Document HSC 11)

Chiu continued to express support for Odim in a follow-up phone call and a second letter. In the follow-up letter he did state:

> I cannot make a specific judgment regarding his clinical abilities as a pediatric cardiac surgeon, but as I stated in our telephone conversation, he has gone to Boston Children's Hospital for a clinical fellowship, and I have no doubt that he has benefited from further exposure to complex pediatric cardiac surgical cases available there. (Exhibit 45, Document HSC 23)

Mulder, the chairman of the Department of Surgery at McGill and Montreal General, sent Blanchard a letter on September 2, 1993. In it he wrote:

> I would rank Jonah as a good clinical cardiovascular thoracic surgeon who wishes to carry out a combined adult and pediatric practice in an academic centre. He has the ability to carry out independent research. (Exhibit 45, Document HSC 14)

He went on to say:

> He has good leadership skills and I think has all the potential to become an outstanding academic cardiovascular thoracic surgeon. (Exhibit 45, Document HSC 14)

In a second letter on November 11, 1993 (written after an offer of employment had been made to Odim), Mulder wrote:

> Technically he was not as mature as some of the other residents have been but he improved on a gradual basis and at the completion of the program we all felt that he was a competent cardiothoracic surgeon. (Exhibit 45, Document HSC 28)

Mulder suggested that Blanchard contact Dr. Aldo Castaneda, Odim's supervisor in Boston. Blanchard tried, but Castaneda was out of the country. As a result, he never spoke with Castaneda or anyone else at Boston Children's.

A letter dated November 24, 1993, from Tchervenkov to Blanchard, contained the following comment.

> As far as training goes, he has certainly had more than enough. As far as whether he can really be successful at today's pediatric cardiac surgery approach, that is always the question for anyone until they actually prove themselves. I have seen, what were considered excellent surgeons with excellent training in pediatric cardiac surgery bomb out. (Exhibit 245)

He concluded the letter by noting that, as a single surgeon in Winnipeg, Odim would have a rough start.

Blanchard said that he never received any indication from Chiu, Mulder, or Tchervenkov that Odim was in any need of remedial training. A review of Odim's training and experiences prior to Winnipeg led Blanchard to a simple conclusion:

> Here we have a brilliant person. (Evidence, page 36,424)

Odim returned to Winnipeg in the fall for a second round of meetings with HSC staff. It was at this point that Collins informed him of his intended departure from the VCHC on October 31. It was also at this point that Odim learned that Pelech was leaving. Blanchard and Unruh had been recruiting a surgeon for a fully operational program, led by a veteran medical director and staffed with three cardiologists. In fact, the surgeon they were hiring would be coming to work at a centre that had only an acting medical director, who was also its only cardiologist.

Surprisingly, it was Odim who informed Blanchard that Collins was leaving. It was not clear when, or if, Blanchard was ever informed of Pelech's departure. Blanchard said that it was not until February 1994 that he discovered that there was only one cardiologist at the VCHC.

In September 1993, Odim and Blanchard entered into serious negotiations. Arrangements were being made to give Odim a cross-appointment to the University of Manitoba's Department of Physiology to allow him to continue with the muscle research he had started under Chiu.

Besides arranging Odim's research, Blanchard and Unruh had to devise a method that would pay Odim a competitive income of approximately $250,000 a year. They managed to do this through a special agreement with the Dean of the Faculty of Medicine, the President of the University of Manitoba, and the HSC administration. Unruh said he believed that Odim had been in a strong bargaining position and had bargained effectively.

As these discussions were taking place, Blanchard made an effort to recruit Tchervenkov to Winnipeg. He offered Tchervenkov the position of head of cardiovascular and thoracic surgery, the position that Unruh held on an acting basis. Had the hiring gone ahead, it would have placed the need to hire Odim in doubt. It also, interestingly, amounted to a change in the strategy of hiring a recent graduate, to one of hiring a surgeon in the prime of his career. Tchervenkov, however, declined the offer.

A formal offer was made to Odim on November 9, 1993 (Exhibit 45, Document HSC 25). One week later his appointment was confirmed. It was signed by Blanchard, Sutherland and the Dean of Medicine, Dr. N. Anthonisen.

The Boston references

Dr. John Mayer, Jr.,[2] was one of the surgeons at Boston Children's Hospital under whom Odim received his training. Mayer estimated that he would have been the attending surgeon for about a quarter of the operations that Odim was involved in while at Boston. In his testimony to this Inquest, Mayer stressed that the assessment of an individual trainee's skills is not absolute, because at that stage in their career people have a capacity to continue to grow and develop. That said, Mayer offered the following assessment of Odim's performance at Boston.

> I would say in the spectrum of people that we have seen, you know, at ten residents a year, or at that time—it is almost ten years, having seen 100 cardiothoracic surgical trainees go through, I would have to say I would not have put him near the top of the group of the people that we had seen. (Evidence, pages 46,044–46,045)

Mayer said he was not entirely convinced that Odim had fully grasped some of the concepts that were being employed. From a technical standpoint, he said:

> I was never that comfortable helping him do anything more than relatively simple and straight forward cases, simply because I was not comfortable with his level of technical skills. (Evidence, pages 46,045–46,046)

In the case of Norwoods, he said all he would have allowed Odim to do was open and close the chest, and it was unlikely that he would have allowed him to perform the complete cannulation process on his own.

The actual resident evaluations at Boston Children's Hospital were informal and were done by Castaneda, the program head. Mayer said he never spoke with Odim about his progress at Boston Children's Hospital, nor about the sort of institution he should consider going to after graduation.

Odim's training at Boston Children's Hospital was one of his main qualifications to justify his assumption of the job as the sole pediatric cardiac surgeon at the Variety Children's Heart Centre. Castaneda's name appears on his list of references. However, no one ever successfully contacted Castaneda or any other of the doctors under whom Odim trained in Boston.

Mayer said that if he had been contacted, he would have said that Odim "was not among the stronger candidates that we have ever seen come through our program." (Evidence, page 46,055) He said he would have rated his clinical knowledge as being from fair to good.

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[2] Dr. John Mayer graduated from Yale University School of Medicine in New Haven, Connecticut, in 1972, interned at the Department of Surgery at the University of Minnesota in 1973, was a medical fellow in the Department of Surgery at the University of Minnesota from 1973 to 1979, and from 1979 to 1981 was a fellow of the division of thoracic and cardiovascular surgery at the University of Minnesota. He received academic appointments at the University of Minnesota, as well as the universities of South Alabama and Harvard Medical School.

At the time of his testimony, Mayer was a professor of surgery at Harvard Medical School. In that capacity, he had directly monitored and supervised the training of Dr. Jonah Odim.

In his testimony, Mayer described the pediatric cardiac surgery program at Boston Children's Hospital. The centre's four surgeons perform an average of between 900 and 1,000 operations a year. There is a pediatric cardiac intensive care unit. The nurses work only on pediatric cardiac surgery, the perfusionists provide services only for pediatric cardiac patients and the anaesthetists work only on pediatric congenital heart cases. A tremendous amount of expertise and skill is focused on this one area.

Mayer was of the view that it would be very difficult for a young surgeon to move from this atmosphere to a much smaller centre, where he or she would be the senior surgeon responsible for restarting a program.

> And I think to go someplace and start it up from scratch is an extraordinarily challenging undertaking.
>
> I have been to some places where I have been asked to go and review programs in certain centres in the United States, where I think this is not an uncommon theme that, you know, people will have had some experience perhaps in one facet of the management of congenital heart disease, a cardiologist or surgeon, or one group, and think therefore they can recreate what they had in their original training centre very simply and easily. In fact, it's a fairly sizable undertaking to assemble the organization and the group of people who play on this team, who have to provide the services. And I think that this notion of the group functioning as a team is an absolutely critical aspect of optimum management of children with congenital heart disease, particularly babies. (Evidence, pages 46,061–46,062)

Before a young surgeon were to take on this responsibility, which Mayer described as "jumping off into the most complicated end of the spectrum," he said there should be a critical assessment of the centre's capabilities and the surgeon's capabilities, both as a surgeon and as a team leader.

> I can tell you that having been a few places where people bit off big chunks and then had quite a bit of difficulty, that that is a common theme, that there was not an appreciation of what it really takes from the whole team perspective to be able to carry off the kinds of complicated things that have to be done. (Evidence, page 46,063)

HSC reference questionnaires

The HSC sends reference questionnaires to those persons whom a job applicant has listed as references. In the case of Odim, the questionnaires were sent to Chiu, Mulder and Tchervenkov. All three men gave Odim a positive assessment, ranking him as being very good in almost every category. Two of the three, however, rated him as being good (as opposed to very good) in his clinical competence. While it is not clear when the questionnaires were sent to the referees, they were not completed and returned until late February 1994, long after Odim had received his appointment with the HSC. The one person on the list of references provided by Odim who was not contacted was Castaneda.

It would be safe to say that Odim's recruitment and hiring was marked by flawed procedures.

No one spoke with the people who had been most recently involved in Odim's training at Boston. Considering Mayer's very lukewarm assessment of Odim's surgical skills, it is conceivable that Odim might not have been hired had that type of information been in the hands of those making the hiring decisions in Winnipeg in 1994. The failure to watch and observe Odim actually performing surgery, or to speak with anyone who had recently performed surgery with him, provided only an incomplete impression of Odim's surgical abilities and his ability to get along with other personnel in the operating room. That proved to be an extremely important issue as 1994 passed.

WHO WAS IN CHARGE?

Before moving on to the events of 1994, it is worthwhile to review two points: the approach that was taken to restarting the program and the degree of confusion that existed as to who had responsibility for Odim's surgical performance.

It is worth comparing the 1994 restart with the manner in which Barwinsky and Collins handled Duncan's arrival. In that case, a senior surgeon with considerable experience in pediatric cardiac surgery and a senior cardiologist believed that it was crucial to move the program forward at what could best be described as a very deliberate pace. They were determined to make sure that the problems associated with de la Rocha's tenure did not recur.

While it appears that many senior figures at the HSC in 1994 believed that such a pace was appropriate, they also believed that someone else was responsible for ensuring that the pace was followed.

This relates as much to the confusion over the lines of authority as it does to anything else. Odim said:

> I knew I had been recruited to replace Dr. Kim Duncan in the established program. I knew that I was under the aegis of the Department of Surgery and the Department of Cardiothoracic Surgery, therefore, I reported to Dr. Blanchard and Dr. Unruh. I knew that I was also a physician in the Variety Heart Centre and reported to the chief of that centre, which was Dr. Giddins.
>
> *Q.* You said, okay, Dr. Giddins, right?
>
> *A.* So it was sort of a three-pronged or three-headed relationship through cardiac surgery, the Department of Surgery and the Variety Heart Centre. And I guess you could add a fourth head, Dr. Wiseman, as the surgeon in chief of the Children's Hospital. And I was one of the—so these were my bosses, at least my perception of who my bosses were. (Evidence, page 23,937)

On the need to phase a new surgeon into the program, Unruh said that he was not disturbed by the fact that, aside from the first six months of 1993, Odim had largely been away from surgery for four years when he came to Winnipeg. He said he expected that Odim would have the insight to recognize that he had been away from the operating room for a while and would act on this insight. As a result, he never passed these views on to Odim. While he believed that it was important for someone in Odim's position to phase himself into surgery slowly, he did not think it was necessary to communicate this view to Odim. Nor did he speak with Giddins about the start-up of the program.

> The unit had functioned so well up until that point in time that I really didn't have an understanding of the relationship between the cardiologist and the surgeon. I assumed that Dr. Giddins would take the leadership role that had been given to him and would phase in the program. But I never specifically gave any directives to him as to how to phase it in. (Evidence, page 35,038)

Unruh's job description makes no differentiation between adult and pediatric services. However, Unruh said:

> I didn't have any direct responsibility. That historically and de facto went to the program, so I didn't have any direct responsibility, but I ultimately did have some responsibility for the surgical aspects of that program. (Evidence, page 37,735)

Unruh said he believed that Giddins would be responsible for Odim. However, he never confirmed that understanding with Giddins. In his testimony, Giddins said he believed that Unruh was responsible for the surgical program. He believed his responsibility was for medical care, not surgical. He said:

> I think my responsibility is to ensure that that process by which that the patient gets to the operating room is appropriate, and to the best of my knowledge, that that operating room that the patients are headed to is capable. (Evidence, pages 36,405–36,406)

Unruh further testified:

> I saw my responsibilities as ensuring there was an acceptable peer review process in place. That peer review process was somewhat unique in this situation because we were bringing a surgeon in to a multi-disciplinary program. The responsibility which I exercised over other cardiac and thoracic surgeons was not exercised to the same extent over Dr. Odim, because I had delegated de facto that responsibility to the Director of the Variety Heart Centre. That is how I saw my responsibility. (Evidence, pages 37,858–37,859)

This was not a view that Giddins shared.

Blanchard told the Inquest that, when Odim arrived, he encouraged him to focus his work on completing his Ph.D. and not become overwhelmed by clinical matters. However, Blanchard also never met with Odim and Giddins to discuss their plans for restarting the program.

It would be fair to say that at the institutional level, the Pediatric Cardiac Surgery Program had a number of problems relating to both planning and communication. When the rough start that Tchervenkov had worried about materialized, other planning and communication problems impeded an efficient resolution of the ensuing issues.

Chapter 6

THE RESTART OF PEDIATRIC CARDIAC SURGERY IN 1994

JANUARY 1, 1994, TO MAY 17, 1994

PROBLEMS FROM THE BEGINNING

1993 had been a hard year for the Pediatric Cardiac Surgery Program at the Winnipeg Health Sciences Centre (HSC). The program had lost its director, its surgeon and all but one of its cardiologists. In retrospect it appears that there was confusion as to who was going to be responsible for monitoring and assessing the new surgeon's surgical performance. Finally, the hospital was in the throes of a large-scale structural re-organization that engaged the attention and energies of many key people involved in the Pediatric Cardiac Surgery Program.

Stemming partially from these difficulties, 1994 was to be a year of tragedy for all associated with the program. Twelve children died, conflicts arose among many of the people involved with the program and, by the end of the year, hospital officials had moved to suspend it. The program has never been restarted.

This chapter describes and discusses the events of the first four-and-a-half months of 1994, concluding with the events of mid-May 1994, when the entire group of pediatric cardiac anaesthetists at the HSC announced that they would not provide service to the program unless a review was undertaken. In particular, the chapter focuses on five children who died while undergoing, or shortly after undergoing, pediatric cardiac surgery at the HSC. Those deaths in particular seem to have been at the centre of the anaesthetists' decision.

However, the events of 1994 must be seen as being more than a series of discrete operations with successful or unsuccessful outcomes. While each child's experience with the pediatric cardiac surgery program was unique, a number of issues arose during the investigation of each case, and many of them repeated themselves. These include a lack of preparation and orientation before the resumption of surgery in February, the lack of attention to building and maintaining a functioning team, problems with decision-making (particularly in terms of case selection), questions of experience and skill levels, confusion over roles and responsibilities, a lack of monitoring of the program and a lack of post-operative analysis of problems.

These are complex and inter-related issues and they do not always lead to simple conclusions. For this reason, this chapter will also discuss in detail many issues concerning the structure and functioning of the Pediatric Cardiac Surgery Program in general, as well as examining five individual deaths.

THE START-UP

JANUARY 1994

When Dr. Jonah Odim accepted a position with the HSC in November 1993, it was expected that he would take up his appointment in January 1994. His arrival however, was delayed until the beginning of February. Odim had to complete research work he was involved in at Harvard, as well as arrange a move to a new city. As an American citizen, Odim also had to acquire a work permit from the Canadian government. Before a permit would be issued, the HSC had to demonstrate to federal immigration officials that it had tried to find a suitable Canadian for the position and that there were none. At one point, HSC officials had to seek the assistance of provincial politicians to resolve the matter.

Orientation and integration

Dr. Robert Blanchard, head of the HSC Department of Surgery, and Dr. Agnes Bishop, head of the Department of Pediatrics, were the line managers responsible for the PCS program. The program faced the following difficulties:

- The VCHC had only one cardiologist
- The director of the Variety Children's Heart Centre was a junior cardiologist who only held the position in an acting capacity
- The surgeon was at the start of his career and new to the HSC
- There were no other pediatric cardiac surgeons on staff to mentor or monitor Odim
- The rest of the surgical team had not worked together for six months.

It is worthwhile addressing the issues identified above in detail.

The VCHC had only one cardiologist

Where there had once been four cardiologists at the VCHC, there was now only one. That one cardiologist, Dr. Niels Giddins, had a large clinical workload and very few people to whom he could turn for support. He would have been extremely overworked for the first half of 1994, if his only responsibility had been to provide cardiology services. However, he was also the acting director of the VCHC.

Giddins was so busy that, even after the program gained access to a transesophageal echocardiography probe in 1994, he did not have the time to become familiar with its operation.

The director of the Variety Children's Heart Centre was a junior cardiologist who only held the position in an acting capacity

No evidence was presented to this Inquest to suggest that Giddins was ever properly prepared for the responsibilities that he had to shoulder when he took over the position of medical director of the Variety Children's Heart Centre.

The VCHC was largely the creation of Giddins's predecessor, Dr. George Collins. A senior cardiologist, with international experience, Collins had shaped the Centre and had been able to act as a mentor to the other cardiologists and to the previous surgeon, Dr. Kim Duncan. Perhaps without fully realizing it, the heads of surgery and pediatrics had allowed Collins to exercise monitoring functions that were properly theirs. It does not appear that anyone ever directly told Giddins that he was responsible for supervising surgical outcomes in the program, a responsibility for which he lacked both the time and experience. Giddins said that he was "never given a distinct list by Dr. Collins or Dr. Bishop of a formal set of administrative responsibilities." (Evidence, page 3,303)

Bishop did recognize that Giddins was being asked to shoulder a considerable burden, for she relieved him of many of his HSC and University of Manitoba duties.

The surgeon was at the start of his career and new to the HSC

Odim was not a newcomer to surgery. He had trained in a number of major urban hospitals in North America. However, he had limited experience as a primary surgeon, had rarely acted in a supervisory capacity and had never held a senior position before coming to Winnipeg. On the face of the evidence, it is clear that he had also always worked in large programs, with access to considerable resources. While the HSC is by no means a primitive institution, its pediatric cardiac surgery program did not have the same caseload nor the same resources as had been available to the program in Boston, where Odim had most recently trained.

As events developed, it also soon became apparent that there were institutional protocols at the HSC that differed from those in the institutions where Odim had trained. These differences were to lead to confusion and, at times, conflict, between Odim and the other staff at the HSC. These conflicts might have been avoidable with a proper orientation session, since it appears that Odim often became aware of the HSC's protocols only after the fact.

In some measure, Odim must take responsibility for this lack of familiarity with the HSC's limitations and differences. He ought to have taken it upon himself to become fully aware of the limitations and peculiarities of the HSC. He need not have accepted them; there may well have been good reason for change. However, as the service chief, he should have known of them before the team resumed surgery in February. In fact, in a number of instances, Odim rejected more than one opportunity to learn more about the peculiarities of the HSC or shape the program to fit his image of how a program ought to run. These opportunities will be discussed in this chapter.

However, of greater concern is the fact that no one in the HSC appears to have undertaken to provide Odim with an organized and systematic orientation. Duncan, Odim's predecessor, had not been asked to provide a written orientation that could be given to whoever succeeded him. Nor, it appeared, did Odim ever contact Duncan to gain any insight as to what he could expect in Winnipeg.

There were no other pediatric cardiac surgeons on staff to mentor or monitor Odim

Odim was also assuming a position that was unique within the structure of the hospital—one that lacked the usual support associated with surgery in other surgical programs. Neither Blanchard nor the acting head of cardiovascular and thoracic surgery, Dr. Helmut Unruh, were pediatric cardiac surgeons. The only experienced pediatric cardiac surgeon to assist Odim, if he should face any technical or clinical difficulties, was Dr. Jary Barwinsky, whose own experience did not include operating on neonates and small children.

In light of these issues, the situation in early 1994 therefore clearly called for a careful reintroduction of pediatric cardiac surgery. Attention should have been paid to both mentoring and monitoring Odim and Giddins, as they took on new and difficult responsibilities. Instead, it appears that in large measure both men were left to sink or swim. Blanchard, Bishop and Unruh did not appear to appreciate the sudden loss of the leadership role that Collins had played at the Centre. They appear to have assumed that the VCHC would simply continue to run without their direct involvement, even though it now had a new and overworked director.

There were a number of factors that contributed to the lack of attention paid to orientation. The major players overseeing the PCS program at the beginning of 1994 were either distracted by other matters or were under the impression that other persons were seeing to such an orientation. In addition, Bishop was immersed in other pressing issues, particularly the changes being implemented by the hospital as a result of the Curran Report.

In short, no one appeared to believe that it was his or her responsibility to plan for the orientation and integration of the new surgeon. As department heads, Blanchard and Bishop must bear the responsibility for this failure. In addition, both Unruh and Giddins should have taken steps to develop a planned orientation and integration. At a broader level, however, the administration of the HSC as a whole should have ensured that there was a more formalized orientation of new doctors. The practice of the HSC in 1994 was to leave such matters to the initiative of individual department heads. Many contemporary institutions, on the other hand, provide a more structured orientation for all new staff.

There was a second orientation issue that needed to be addressed. Not only was the changeover from Duncan to Odim poorly handled, but the changeover at the top of the Variety Children's Heart Centre from Collins to Giddins was also not well managed.

FEBRUARY 1994

The restart of the program

Odim took up his duties on February 14, 1994, and performed his first operation on February 28. By March he was performing very complex operations. Until May 1994, when the program was reduced in scope, it would appear that only one pediatric cardiac surgery patient was referred out of province. When compared with the way that Collins helped to ease Duncan into his role as a pediatric cardiac surgeon, this has to be seen as a very rapid start.

Three inter-related issues from this period are deserving of discussion. These are the lack of attention that was paid to team building, the cool response that was given to those nurses who sought orientation sessions to prepare themselves for working with Odim and the approach that was taken to case selection.

Team building

Operations are not performed simply by a collection of individual professionals, but by teams, which require a high degree of trust and strong communication. Teamwork improves over time, through the experience of working together. For this reason, any time there is a hiatus or a new member is introduced to the team, particularly as key a member as the surgeon, the team must undergo a process of rebuilding. As was noted in Chapter Five, the pre-surgical preparation set up at the VCHC by Duncan and Collins involved a series of meetings where team members prepared as a team for the forthcoming surgery. In addition, there were post-operative meetings that served as a forum for discussion of outcomes. Collins and Duncan had worked hard to develop a feeling of trust and open communication, as they recognized that without these, such meetings could easily turn into acrimonious encounters or simply become routine events where difficult questions were avoided and not addressed.

It is worthwhile comparing the startup of February 1994 with the sort of team building that had taken place under Collins. After de la Rocha's departure, Collins and Barwinsky had spent a number of months preparing for the restart of pediatric cardiac surgery. During this preparatory period, steps had been undertaken to ensure that proper equipment was in place, that staff were appropriately trained and that a general awareness of the program's direction and goals was developed, so that all people 'were on the same page' when pediatric cardiac surgery was recommenced. Collins had organized training sessions with nurses and throughout his tenure had met regularly with the surgeon and other medical personnel involved in the cases to assess how things were evolving. Pre-operative meetings were held at which the types of cases that were going to be scheduled for surgery were discussed and the nature of the various operative procedures was outlined. Opportunities were provided at these meetings for members who were going to participate in the program to ask questions and information was shared. Little of that occurred before Odim began to operate in 1994.

Despite the importance of understanding how a surgical team functions, little attention seems to be paid to the issue by the medical institutions that use teams. That was the case for the Pediatric Cardiac Surgery Program at the Children's Hospital in early 1994.

While Giddins was consumed by his workload, as the acting medical director for the Centre, he held a major responsibility for ensuring that the restart of the program in February 1994 took place smoothly and carefully. Odim, as the chief surgeon for the Pediatric Cardiac Surgery Program, also had a responsibility to do so, but seemed to other staff—especially the nurses—to be oblivious to its importance. The failure to ensure that the program started carefully and methodically was to come back to haunt the hospital throughout the year.

The nurses' attempts to initiate an orientation

Shortly after Odim arrived in Winnipeg, Giddins introduced him at a meeting of senior nursing staff. After that meeting, Giddins believed that Odim would arrange his own meetings with other members of the operating-room team, such as the anaesthetists and the nurses. From the evidence, it appears that Odim did eventually meet with most of the team personnel. However, the meeting with the senior nursing staff amounted to the only event approaching a formal orientation that Odim ever received.

The problems with the lack of a proper startup can best be understood in the light of efforts of members of the nursing staff to initiate a proper orientation session with Odim. Before any operations were undertaken, Odim attended a meeting with heads of each nursing department with whom he was to work. According to Donna Feser, the pediatric intensive care unit (PICU) manager, this meeting was attended by the nursing heads of that unit, the neonatal intensive care unit (NICU), nursing director Isobel Boyle and Joan Borton of the VCHC. Each of the nurses gave a description of how their units operated. Feser testified that at this meeting she informed Odim that the PICU was a closed unit. She also said that at this meeting she asked him about his approaches to post-operative care. She testified:

> I was interested in what he needed from the nursing staff post-operatively, if there was anything special or anything different that we needed to know in order to look after his patients. Because, as we all know from experience, each doctor usually has preferences.
>
> *Q:* Right.
>
> *A:* And will have certain little things that they like to have done, or certain things in place, or certain things available to them. And I asked him, and he said really nothing, nothing special. He did point out, though, that he had information from Boston, that he had some, he had information that he would give us from Boston that detailed pre-op and post-operative care. (Evidence, pages 29,815–29,816)

Feser said that Odim eventually provided her with an academic article written by three doctors. She said this was not the sort of surgeon-specific information for which she was looking.

> What I expected was information on what his expectations were pre-op, what they were post-op, and any additional information that he felt we should know in order to better look after his patients. And after looking through it, it was just another article, it really wasn't helpful. (Evidence, page 29,817)

This was to become a recurring issue for the PICU and the NICU nurses. Feser testified that Odim only visited the PICU ward itself a few days before performing his first operation, and the visit was the result of her prompting.

The NICU nurses had similar experiences with Odim. Senior NICU nurse Joan Armitage said that the staff in the NICU sent a memo to Odim requesting specific information from him about his approach to surgery. She gave this description in her testimony of the type of information that the NICU staff wanted:

> My primary expectation would be that, first of all, Dr. Odim be very specific with us in terms of his philosophies, he needed to tell us that his surgeries were going to be more reparative versus our previous experience had been somewhat more palliative. Therefore, because they were more reparative the children and babies would come back to the units far more critically unstable than we had known before, that we would be dealing with a lot more delayed sternal closures, and that in general the level of our practice would just have to be stepped up just a tiny bit. (Evidence, page 29,413)

She also said she would have expected Odim to present a series of educational in-services to give the NICU nurses an insight into his approach to surgery and post-operative care. Instead, the NICU nurses also received a copy of an academic article. Armitage said it was of no value in preparing the nurses to deal with Odim's patients.

> It was information that we already had had with our previous experience, so it certainly didn't tell us what Dr. Odim's approach would be. (Evidence, page 29,412)

In his testimony, Odim explained that the article had been given to him by Dr. G.W. Wernovsky, a Boston doctor under whom he had trained. Odim had asked him for something he could distribute to his new team to allow them to prepare for working with him. It was apparent from his evidence that Odim never did appreciate the lack of utility of the material he provided to the ICU staff.

The relationship between operating-room nurses and the surgeon must be one in which both have a degree of confidence in and an ability to communicate well with each other. They do not have to like each other, but they do have to be able to work well together in order to accomplish the ultimate objective—doing what is best for the patient. Surgeons must be able to assume that those items essential to the performance of the operation will be present. The nurse must be confident that—emergencies aside—there will be no expectations and demands that are not a usual or expected part of the procedure or have not been clearly communicated from the outset.

Senior pediatric operating-room surgical nurse Carol Youngson sought to arrange meetings with Odim and the OR nursing staff to discuss how he wanted things done for the surgical procedures which he was going to perform. In addition, she attempted to organize a dry run in the operating room. She was, however, largely unsuccessful in her efforts to get Odim to work with her in preparation for the initial operations.

She did manage to arrange a meeting with Odim and others, including Carol McGilton and Karin Dixon (the OR unit manager), before the restart of the program. At the meeting, Youngson had hoped to discuss Odim's surgical preferences and his equipment needs, as well as what sort of differences he might bring from his training in Boston to the Children's Hospital OR. However, instead of engaging in such a discussion, Odim simply presented the nurses with a copy of some preference cards that had been prepared for another surgeon in Boston with whom Odim had trained. He told the nurses that they could use those cards, since they represented the approaches to which he was accustomed.

Preference cards are cards or sheets of paper that outline an individual surgeon's wishes or preferences for individual surgical procedures. On each card, specific operations are identified and a brief description of the procedure is set out, along with a list of equipment that the operating-room nursing staff must prepare and have ready. The cards usually set out how equipment is to be handled and prepared. The preferences can also reflect information specific to the surgeon, such as whether a surgeon is right or left-handed, what size gloves he or she wears, whether the surgeon wishes music to be played in the OR, what type of music and so forth.

The OR nurses usually develop and maintain these cards and use them as a checklist in their preparation for a particular operation and for a particular surgeon. The cards are important tools for nurses to ensure that what goes on in the OR goes as smoothly as possible.

While preference cards were in place for the operative procedures undertaken by Duncan, Youngson had not expected Odim to have his own set of preference cards. Indeed, she viewed the meeting that she had organized as the first step towards preparing a set of cards for Odim.

Youngson soon came to the conclusion that the cards that Odim had given her were not helpful. In her testimony she said at times they gave too much detail, at other times too little. And while Odim may have trained with the surgeon for whom the cards were developed, Odim still had his own preferences, which at times varied from the information on the cards. In addition, the cards referred to equipment that was not yet at the HSC and was in some cases not readily available in Canada.

As a result, Youngson chose to use Duncan's preference cards. As Odim performed each specific procedure, Youngson and her staff would use one of Duncan's cards to prepare for the case, amend the card to take into account what Odim needed and then make up a card for Odim.

Odim demonstrated foresight in having arranged to have a set of preference cards. However, the fact that those cards did not appear to reflect his actual preferences and that he did not take the time to engage the OR nurses in a discussion of his preferences foreshadowed other problems that were to arise.

For example, Youngson asked Odim to consider doing a dry run of an operating-room procedure with the OR staff, but was rebuffed. Youngson wanted a dry run so that Odim could familiarize himself with the physical layout of the OR, where equipment went, how lines were arranged, how and where he preferred to stand and for the OR personnel to acclimatize themselves to Odim's approach. In particular, Youngson believed that the physical space and equipment in Winnipeg would not match Odim's previous experiences.

> American hospitals are almost always very well equipped, at least from what I heard, always have state of the art equipment. You know, we had good equipment, but I don't know that I could call it state of the art all of the time. (Evidence, page 8,345)

Youngson testified that Odim said he did not think a dry run was necessary. He told her that he was prepared to accommodate himself to the way that the operative staff had done things under the previous surgeon and that they would not have to do things differently. If there was a need to change things, he felt that those matters could be addressed as time went on. While disappointed, in Youngson's view, it was not her place to insist that the surgeon participate in a dry run. Considering that the purpose of having one in the first place was to establish a relationship among team members, including Odim, the surgeon's refusal to participate rendered a practice session without him futile in her view.

Youngson also proposed a dry run when she met with Odim and perfusionist Chris McCudden, later in February 1994. Odim recalled that discussion and testified that he would have agreed to a practice run if McCudden and Youngson had insisted, but he recalled that McCudden was uncertain, while Youngson was not insistent that a dry run be done. McCudden recalled that Youngson had raised the matter and that neither he nor Odim saw the utility of such an exercise.

The meeting between Odim, McCudden and Youngson took place in the OR, again at Youngson's instigation. At that time, McCudden and Odim discussed issues relating to perfusion, while Youngson showed Odim the sorts of cannulas and suturing equipment used at the HSC. At that time she again attempted to determine his preferences. According to her testimony, he gave the same response that he had given when earlier asked to participate in a dry run, namely that he would simply work with the existing equipment.

The perfusion team as a whole met with Odim as well, before the restart of operations. At that meeting, Mike Maas recalled that they also offered to conduct a dry run. Odim turned the offer down, saying he believed it was not necessary.

Odim also attended one of the anaesthetists' Wednesday morning rounds, at their invitation, before the start of the surgical program. At what Dr. Ann McNeill described as a casual meeting, Odim said that he would be willing to adapt to their local methods and approaches, as well as making suggestions for changes.

CASE SELECTION

During the period that Collins was the head of pediatric cardiology at the HSC, pediatric cardiac surgery was carried out by three different surgeons: de la Rocha, Barwinsky and Duncan. Collins ended de la Rocha's Winnipeg career because he was not satisfied with de la Rocha's surgical results. Flowing from his experience with de la Rocha, Collins was careful to ensure that the program never again took on cases that were beyond the skill level of the attending surgeon. This meant, if necessary, erring on the side of caution and sending children out of province.

While the HSC was attempting from the outset of Collins's arrival to establish itself as a heart centre capable of treating any and all patients referred to it, in very few years did the program actually do all possible cases. From its inception, the pediatric cardiac surgery program at the Children's Hospital regularly referred patients to other heart centres in the country, including Saskatoon, Edmonton, Vancouver and Toronto.

While it was always understood that cases could be referred out of province, there also seems to have been an inclination not to refer cases away unless there was a good reason for doing so. What those reasons were seem to have hinged on the question of whether or not the surgeon felt capable (or felt the team was capable) of performing the operation in question. According to Collins, he essentially left the question for Duncan to decide, although Collins seemed not to have been too shy about expressing his view as to whether or not a particular case should be done in Winnipeg.

One would have thought that when a new surgeon arrived in Winnipeg, the entire question of which cases would be done here and which would be sent out of province would be revisited. There is some evidence that this was the case. Odim gave this description of the approach that he and Giddins had agreed upon.

> The plan was essentially we would slate the elective cases and we would get a chance to meet families, and then we would tackle the emergencies as they came. So that the program would start up by vetting the elective cases on the slate, meeting with the families, reviewing the data, and booking them. And of course during this period, we would take whatever emergencies came through, like any other service. (Evidence, page 23,948)

Odim said this did not mean they would operate on each emergency, but that they would review it. The only cardiac lesion that Odim said that they expected to have to transfer out (or have an outside surgeon come in to address) was Transposition of the Great Vessels.

Despite Odim's view that this was "understood", there appears to have been remarkably little discussion of this approach with anyone other than Odim and Giddins. None of the anaesthetists could recall Odim or Giddins discussing the matter of case selection with them before operations resumed. The same could be said of the nursing staff, the perfusionists and staff in the ICU. If there was an agreement on the matter of case selection, then the agreement appears to have included only Odim and Giddins.

At the same time, other staff involved in the program said they 'assumed' that the cases the surgeon would be undertaking at the outset would involve only the simplest of lesions. There seemed to be a consensus that the program should and would start off by doing only those cases that presented the lowest risk for morbidity and mortality. However, problems arose when more complex cases were undertaken more quickly than some involved in the program felt was appropriate.

While Odim said the plan was to start with the simpler elective cases, the complexity of the cases being done by the program quickly escalated. Within a month, Odim was performing operations that he described as cases of moderate complexity (the Caribou, Ulimaumi, and Goyal cases, all to be discussed in this chapter). Rather than sending any patients out of province initially, the more complex cases appear to have been simply deferred until later in the program. The problem with deferring pediatric cardiac patients, however, is that eventually—and in some cases sooner than others—the condition of the child will become more critical. In his testimony, Odim said the Caribou and Ulimaumi cases were dealt with because they had become urgent.

At least one member of the VCHC staff was surprised with the lack of formal discussion about the approach that was going to be taken to restarting the program. Nurse clinician Borton testified:

> I thought that we would all sit down and find out what his experience had been in terms of slating procedures. I thought we would decide to do simple to complex cases, in that order. I thought he would want to know what we had done before in terms of pre-operatively, and what our routines were. (Evidence, page 18,121)

This did not take place. Within the first four months, Odim had undertaken a first-stage Norwood reconstruction, a particularly difficult procedure. The decision to offer this operation was undertaken by Odim and Giddins without any prior discussion with the neonatologists or the anaesthetists (or any other member of the surgical team).

Given that both Odim and Giddins were new to their positions in 1994 and quite inexperienced, their department heads—Bishop and Blanchard—ought to have ensured that there was a better plan in place, which would restart the program in a staged manner. There does not appear to have been any such instruction or planning.

SUMMARY

At the end of February 1994, the pediatric cardiac surgery program resumed service. While the resulting problems were not yet fully apparent, the program's structure was clearly flawed. Lines of authority were fractured, team members had not had a chance to develop trust or confidence in one another—indeed, difficulty with communication was already emerging as an issue. Other issues that could have been identified at this point, such as Odim's concern with the number of anaesthetists or the limitations of the ICU wards, had not been properly flagged. These problems stemmed from the fact that the Department of Surgery and the

Department of Pediatrics had not provided Odim with a strong orientation, while, at the same time, Odim appears to have declined to benefit from the more informal opportunities that had been presented to him.

SURGERY FROM FEBRUARY 28 TO MARCH 14

FEBRUARY 28 – THE CASE OF ST

On February 28, 1994, Odim performed his first surgical procedure in Winnipeg. The patient was a young girl named ST. (In this report, references to children other than the 12 who are the subject of this Inquest will be by initials.) In a closed procedure, Odim tied off a patent ductus arteriosus and repaired an aortic coarctation. The case proceeded smoothly and team members were encouraged by its success. It should be noted that in 1994 over 70 children underwent pediatric cardiac surgery at the HSC. Many of those cases passed without any significant incident. For that reason they are not discussed in this report. From this point on the report will discuss only those cases that give rise to comment.

MARCH 7 – THE CASE OF DR – THE FIRST OPEN-HEART CASE

DR was born on August 23, 1981. When she was nine years old, she was diagnosed with an atrial septal defect and was referred to the Variety Children's Heart Centre for evaluation. On March 7, 1994, DR underwent an operation to close the ASD.

Odim operated on DR one week after performing his first surgical procedure in Winnipeg. This was the first open-heart case he performed in Winnipeg. It was during this procedure that a number of events arose that caused concern for some members of the operating team. The three issues that arose were Odim's lack of familiarity with the OR setup, his problems with cannulation and his treatment of nurses.

Odim's lack of familiarity with the OR setup

In preparing to go on bypass, the surgeon must connect the patient to the cardiopulmonary bypass machine through a series of lines. In Winnipeg the surgeon, after connecting one end of each of the lines to the patient, generally handed most of the lines to a scrub nurse, who handed them to the perfusionist, telling him what each was for. In turn the perfusionist connected the lines to the appropriate bypass machine ports. Because of the cramped nature of the operating room, the surgeon handed some lines directly to the perfusionist, who was generally situated behind the surgeon.

During this operation Youngson concluded, to her surprise, that Odim was having considerable difficulty with the mechanics of the process.

> It was just that Dr. Odim didn't seem to know how this all went. And at that point in time, what went through my mind was, this guy has never done this before. And I thought, no, that can't be true, he has come from Boston and Montreal, he has done all of these cases, he must have had lots

> of experience. But that was the thing that popped into my mind at that point in time. (Evidence, pages 8,359–8,360)

Nurse Carol McGilton also described Odim as having trouble with the lines.

Youngson felt it necessary to assist Odim by, in effect, giving him direction, while McGilton (who was the second scrub nurse) performed a number of tasks that would normally have been undertaken by Youngson.

> He was very polite about it, he thanked me, he seemed appreciative—I won't say impressed by my knowledge, he seemed to acknowledge that I knew what I was doing and sort of went with what I said. I felt kind of odd, I think it was the first time in my experience that I ever told a cardiac surgeon what to do. You know, they don't take to that very well in most instances, so I was a little uncomfortable. (Evidence, page 8,362)

Odim testified that he did not have problems placing the lines but rather asked for guidance from Youngson and chief perfusionist Michael Maas because he was unfamiliar with the setup in the operating theatre. He said that he was trying to modify his approach to the actual physical setup of the OR. He also denied he was confused about how to connect the lines.

In her testimony, Hancock did not agree that Odim seemed not to know where the lines went. She felt that the setup in every OR was different and, since they were a new team, they had to work out all the steps of where things should go. She did not seem to feel that there was anything unusual about the time it took in this case for the lines to be sorted out.

Youngson agreed that Odim did seem to be trying to adapt himself to procedures that were established by his predecessor, Duncan. However, she felt that placement of the lines could have best been reviewed in a dry run, rather than while an operation was actually proceeding and the patient was lying on the operating table with an open chest. There is merit to this view.

Odim's problems with cannulation

Once the lines were in place, the surgeon would perform the task of cannulation. There are different approaches to cannulation. The Winnipeg OR nurses were familiar with the technique that Dr. Kim Duncan had used. In that method, the surgeon placed a clamp on the part of the blood vessel intended as the cannulation site. After cutting a small hole in the clamped portion of the vessel, the surgeon would then slowly release the clamp and insert the cannula into the hole in the vessel.

In the alternative "stab-and-go" technique, the surgeon, without making use of a clamp, would open a hole in the blood vessel with a scalpel and then immediately insert the cannula. This method calls for speed and efficiency. Hesitation or fumbling with the cannula can increase the risk of blood loss.

Youngson, who had never seen the stab-and-go method used on pediatric patients, offered a clamp to Odim when it came time to cannulate. Odim declined to use it, saying he would use the stab-and-go method.

OR staff, such as Youngson, McGilton and McNeill, felt that Odim was not particularly proficient at this form of cannulation. (Even when he used a clamp, which he did later in the year, they thought that he was not proficient at cannulation.) McGilton wondered during the DR case if Odim was nervous or was simply not used to the HSC equipment. Dave Smith, who was one of the perfusionists, noted with respect to other cases the difficulty that Odim had with cannulation, but concluded that Odim was just rusty.

After noting Odim's difficulty with cannulation, Dr. Ann McNeill was sufficiently concerned to mention it to her anaesthetic colleagues. She felt that, as a fully trained cardiac surgeon, Odim should have been quite familiar with cannulation, and that it should have been second nature to him. She felt that before going into surgery, Odim should have taken steps to familiarize himself with the line procedures that were used in the Children's Hospital, as well as the cannulas that were available.

Hancock, however, did not agree with the criticisms levelled at Odim's cannulation technique. She felt that Odim did know how to cannulate adequately, although she did notice that he sometimes cut the purse-string sutures that were designed to hold the cannula in place and would have to put in new ones. Some of his cannulations were difficult, she said, but she did not believe that Odim's cannulation technique compromised patient safety. She did, however, concede that he needed to improve in this area. She said that if she had had a serious concern with Odim's cannulating techniques, she would have discussed her concerns with him.

Odim said he used the stab-and-go method only for cannulation of bigger children and adults. He said he did so because their aortas can be somewhat calcified and the use of a clamp can crack the calcium and send debris into the bloodstream (and possibly up to the brain). For babies and small children, he said, he always used a clamp to cannulate. Dr. Heinz Reimer (an anaesthetist who worked on several of Odim's cases) and Hancock both recalled that Odim did not start using the clamp technique until halfway through the year. Odim disagreed with that recollection.

While Odim also disputed the evidence of those who expressed concern about his cannulation abilities, he did say that before the DR case, he had last cannulated a child in Boston three months earlier, in December 1993. He acknowledged that he had been doing predominantly clinical research during the last six months of his training in Boston. As a result, he had cannulated only once or twice a month during that period. He disagreed, however, with the suggestion that he was rusty at cannulating.

OR staff at the Children's Hospital had been used to Duncan's method of cannulation, which involved the use of a clamp. Odim's use of a different technique cannot be questioned on the basis that the technique might have been inappropriate. The question of what approach to use to cannulate a child is clearly one best left to the individual surgeon. However, it does seem that there were questions about Odim's mastery of the technique that he did employ.

The issue of Odim's cannulation technique and whether or not he was proficient in it was raised again and again during the course of the proceedings, particularly with regard to several of the 12 patients whose cases were investigated. Poor cannulation can lead to significant blood loss, which is very serious in young children, who have small volumes of blood. Many of the children whose cases are discussed in this report suffered from a variety of blood-loss related problems.

In addition, problems with cannulation can lead to interrupted procedures if cannulas have to be reinserted. Any lengthening of the time of a procedure increases the risk of complications to the child. Finally, if cannulas are not properly inserted, there can also be problems with blood flow to and from the bypass machine, which can create a variety of additional problems for the surgical team to address.

The OR staff at the Children's Hospital of Winnipeg were unprepared for Odim's particular approach to surgery in general and were unimpressed with his cannulation ability in particular. These facts undoubtedly were significant contributors to the lack of confidence that team members quickly developed in their new surgeon.

Odim's treatment of nurses

Odim's dealings with nurses were to prove problematic throughout 1994. During the course of the year, he and a number of nurses developed antagonistic relationships. The antagonism generally related to differences in opinion about medical issues. However, the relationships also concerned more personal matters. Witnesses testified that, shortly after the restart of the program, Odim made a number of comments that were sexist and of a sexual nature to some of the nurses. Those comments were unprofessional and offensive and, in the context of the hospital setting, demeaning to the nursing profession. Much of what was said during the course of those conversations was heard *in camera*, and is not worthy of repetition. While Odim testified that he had no recollection of having made these comments, the specificity of the recollections of the numerous witnesses who overheard them, and the vagueness of Odim's denials, all combine to bring about the conclusion that Odim made the remarks as alleged.

Odim also came to resent the way he felt the nurses, and Youngson in particular, tended to compare him with Duncan. This led him to make a number of sarcastic and inappropriate comments about the relationship between the nurses and his predecessor. When operations were not proceeding smoothly, Youngson testified that Odim would turn to her and say he was sure that this was not the way that Duncan would have handled the case.

On another occasion, in an obvious reference to Duncan, Odim sarcastically asked Youngson, in front of other members of the operating team, if she had heard from her "beloved" recently. Odim's comments could have done little but create a distrustful and negative atmosphere between him and the nurses. Other remarks made by Odim later during the year also contributed to this atmosphere.

THE CASE OF GARY CARIBOU

ISSUES

Gary Caribou's death, on March 15, 1994, was the first death under consideration by this Inquest. His case gave rise to the following questions:

- Was there an inappropriate delay between the time of his diagnosis and the date of the operation on his heart?
- Was his mother provided with sufficient information to allow her to give informed consent to the procedure?
- Was Gary healthy enough to undergo an operation?
- Did the length of surgery contribute to his death?

- Did a post-operative abdominal drainage procedure contribute to his death?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Gary Caribou was an Aboriginal child, born on August 22, 1993, to Charlotte Caribou and Morris Dell of Lynn Lake, Manitoba. His birth appeared normal and without complications.

In November 1993, Gary's mother took him to the Lynn Lake Hospital because he was having difficulty breathing. A chest X-ray showed that he had pneumonia and Gary was treated with an antibiotic and a bronchodilator, both of which seemed to provide some relief for his wheezing and laboured breathing. Dr. Trevor Schlam also identified a heart murmur and referred Gary to Dr. M. Levy in Thompson. In his letter of referral, Schlam asked Levy to check for a congenital heart abnormality and further examine Gary's respiratory problems, which Schlam thought might be cardiac in origin.

Throughout Gary's treatment there were to be differences of opinion amongst all the doctors as to whether the respiratory problems that Gary experienced were solely attributable to his heart condition or if they were due to lung disease.

Gary was transferred to hospital in Thompson on November 30 and stayed until December 3, 1993. He was in respiratory distress and did not respond to bronchodilators or antibiotics. He was also diagnosed with failure to thrive. This is a state of poor health that describes a child's inability to grow and develop in a normal manner and is often associated with heart abnormalities. Children suffering from failure to thrive are susceptible to illnesses and diseases, in addition to the heart problems they might have. The condition needs to be closely monitored to ensure that the child does not deteriorate further.

Doctors in Thompson concluded that Gary had symptoms and signs of heart failure, brought on by a large ventricular septal defect with a fairly large shunt. Tests showed his heart was enlarged. He was treated with diuretics and seemed to improve, with a decrease in his respiratory distress. An appointment was arranged with the Variety Children's Heart Centre.

On December 17, 1993, Giddins saw Gary at the VCHC. By December 20, Giddins confirmed that Gary had:

- a moderately sized ventricular septal defect
- mild enlargement of both ventricles
- a muscular right ventricular outflow tract with muscle bundles.

He noted that there was a large left to right shunt, allowing blood to move inappropriately through the hole between the ventricles. Muscle bundles develop when portions of the heart are required to work harder than normal. These bundles can block or limit the flow of blood in an unhealthy manner, but in Gary's case, there was no actual obstruction to the outflow of blood from the right ventricle (or outflow tract obstruction). Muscle bundles also have implications for cardiac surgery, as their presence can make it more difficult to perform certain operations.

On examination in clinic, Giddins found Gary to be in heart failure. Gary's liver was enlarged. He was also small for his age, weighing only 5.5 kilograms, instead of an expected 6.5 kilograms. Giddins increased the dose of Gary's diuretics and also started him on digoxin, a drug used to treat congestive heart failure by strengthening heart contractions. Giddins did not recommend surgery at that point. He believed that if Gary was treated with aggressive nutritional support, he might grow out of the problem. While he suggested a follow-up assessment in two months, Giddins also added a caution: "The prognosis must be considered to be uncertain." (Exhibit 5, page CAR 2)

Giddins relayed his conclusions to the doctors who had referred Gary to him. However, there is no indication of what Giddins related to Gary's parents at that time. Charlotte Caribou testified that on this initial trip to Winnipeg, she was informed that Gary had a hole in his heart and that the options were to let it close on its own or to perform surgery. She said that Giddins essentially made the decision in favour of waiting. She returned to her home community with the expectation that she would be called back for another appointment.

Charlotte Caribou was not very knowledgeable as to her rights as her son's legal guardian, nor, if her conduct and demeanour on the witness stand is any indication, would she have been very assertive about them. She had spent most of her life in the remote Northern community of Mathias Colomb First Nation. While she was quite conversant in English, she had limited education, and spoke primarily Cree. Furthermore, she had had limited or no experience with this type of situation. As with many people, she said that she relied almost totally on the medical authorities.

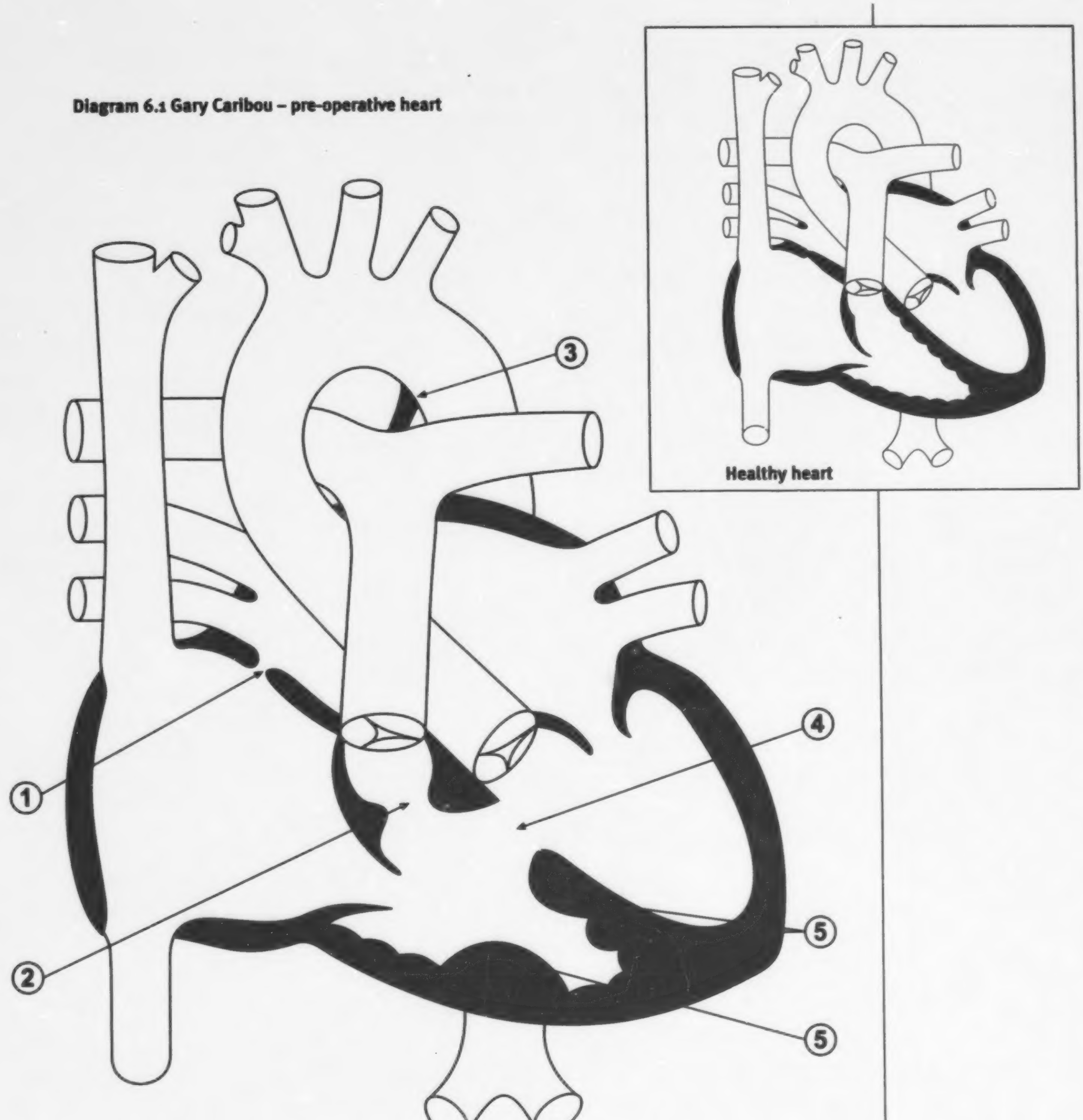
Gary returned to Lynn Lake, where he was re-admitted to hospital on December 27, 1993. There he was treated for two months for failure to thrive and congestive heart failure. During this period, Schlam remained in touch with Giddins and the VCHC. Gary was unable to suck the volumes of formula required to increase his weight. A tube was therefore inserted through his nose and down into his stomach, so that larger volumes of formula could be given through the tube. When attempts were made to give him bolus feeds (or a larger volume at one time), Gary vomited. To prevent further vomiting, he was placed on continuous feeds through the tube into his stomach. This degree of forced feeding had limited success.

THE DECISION TO OPERATE

The possibility of Gary growing out of his heart condition depended on his increasing in weight and size. His low weight, small size, and poor breathing were associated with his poor heart function. Therefore, it is noteworthy that Gary's condition did not improve significantly during the intervening period. He suffered two episodes at the hospital where he had a high fever, although tests did not show that he had developed an infection. He was, however, treated with antibiotics during this period. (In fact, he was receiving antibiotics when he was admitted to the Children's Hospital for surgery.) Gary's increased expiratory wheezing also disturbed the doctors in Thompson. They were not able to determine if his apparent asthma originated from his heart or from a problem in his lungs (Exhibit 5, page CAR 58).

Gary was transferred to the HSC in Winnipeg for assessment on February 28, 1994. On admission to the HSC, his weight was up approximately one kilogram from his December 1993 weight of 5.5 kilograms,

Diagram 6.1 Gary Caribou – pre-operative heart



1 – Patent foramen ovale
2 – Right ventricular outflow tract obstruction
3 – Ligamentum arteriosus (former ductus arteriosus)
4 – Ventricular septal defect
5 – Abnormal right ventricular muscle bundles

but he was still far below the normal weight for a child of his age. On admission the doctors could hear a great deal of wheezing throughout both lungs, although Gary had fairly good air entry into both lungs.

Gary's case was presented at the March 7 pediatric cardiac surgery conference. A heart catheterization done that day confirmed the earlier findings. However, the catheterization study also demonstrated significant muscle bundles in the right ventricular outflow tract. Odim concluded that surgery was necessary to correct the VSD, which he did not believe would close on its own. He believed Gary was showing signs of congestive heart failure. Odim predicted a stormy course for Gary's recovery because of his frail condition. This would be the first time that Odim would undertake such an operation on his own. It would also be the most difficult case the team had undertaken under Odim's direction to that point.

None of the medical consultants retained by the Inquest disagreed with Giddins's and Odim's diagnosis. Dr. Gary Cornel testified that he believed that by March 7, surgery was the only reasonable choice. He did suggest that Gary was in better condition for surgery earlier than he was on March 14, when surgery was actually performed. Since the delay was to see if Gary could be strengthened for surgery, it would not have been wise to wait any further. However, the question remains as to whether or not the operation should have been carried out in Winnipeg.

CONSENT

On March 9, Odim met with Charlotte Caribou. In a letter to Giddins, he said he discussed the surgical plan to close the VSD in detail with her. Odim said he also discussed how the increased pressures in the ventricles and the borderline pulmonary vascular resistance suggested that the post-operative course might be difficult. In addition, Odim said that he explained all the potential risks to Gary's mother. He indicated that she seemed to understand, and that she gave her verbal and written permission for surgery.

It appears that Charlotte Caribou may have been adequately informed as to Gary's cardiac defects. She was aware that he had a hole between his ventricles that had to be patched. Whether or not she understood or was aware of the other issues that made up the risks that Gary faced is an entirely different question. Importantly, she seems not to have been aware of any concerns about Gary's physical strength or his failure to thrive. Also, she was not aware that there were any issues surrounding the team members and their collective and individual experience.

In his testimony, Odim said he did not discuss with Charlotte Caribou his previous experience in performing this operation. He said it was not his practice to discuss his experience, unless the parents specifically asked him about it. He said this had also been the practice of the people under whom he had trained. As noted in Chapter One, in obtaining consent, professional practice is not the sole determinant of the information that must be provided to the patient or the patient's parents.

Odim's surgical practice (as opposed to the period he spent as a surgical resident) was less than one month's duration when he spoke with Charlotte Caribou. This means that he had only been involved in obtaining consents to perform surgery on his own for little more than three weeks. In other words, Odim's habit of not providing information about his experience was not a practice of long standing, but one that he had recently adopted.

When asked if this meant that the onus was on the parents to ask about his experience, Odim said:

> What I'm trying to say is that when I see patients in my office, I don't have a list of my procedures that I have done, a C.V. that I give to my patients as I meet them. We discuss the situation. Many families will ask questions. Some will ask, well, how many have you done; some will not ask how many have you done. It is just not something that's been part of my practice. (Evidence, page 24,069)

Odim said he did not feel that the fact that this was the first time he was performing this procedure as the primary surgeon in a new setting elevated the risk in any fashion. He also said that he did not raise with Charlotte Caribou the possibility of having the operation performed in another centre.

He did acknowledge that experienced surgeons generally have lower risks of morbidity and mortality than do inexperienced surgeons, largely because of the benefits of experience. Odim did not feel, apparently, that such information was something that he ought to have shared with Gary Caribou's mother.

PRE-OPERATIVE CONDITION

While there was little disagreement with the decision to operate on Gary in March, questions have arisen as to whether or not he was in fact healthy enough to undergo surgery. Some of the consulting witnesses who assessed this case raised concerns about whether or not Gary Caribou was suffering from an infection at the time of his operation. If this was the case, then it may not have been appropriate to operate. Cornel, for example, stated that Gary's preoperative status was possibly compromised by an undiagnosed chest infection.

As early as November 1993, it had been noted that Gary was experiencing wheezing throughout both lungs. From the end of December, he had suffered through two bouts of fever while in Lynn Lake and had been treated with antibiotics, although tests had not indicated that there was an infection.

On February 28, when he was readmitted to the HSC, extensive wheezing was again noted, along with moderately severe subcostal and intercostal in-drawing. Subcostal and intercostal in-drawing are indications that a patient is having difficulty breathing. The first seven ribs are attached to the breastbone by costal or rib cartilages. Subcostal means under the rib and intercostal means between the ribs. These terms together describe the situation in which a person's breathing is so difficult that the skin below or between the ribs is sucked in each time the patient takes a breath. Thus, Gary's breathing difficulties were worse than they had been in December.

Gary's liver was also enlarged. This was a sign that he may have had heart failure or he may have had lung congestion from a lung problem that was not related to his heart problem. The enlarged liver could also indicate that, because of the very fast rate at which Gary was breathing, his lungs had become overinflated and were pressing down on his liver.

There was ongoing discussion among Gary's doctors as to whether or not Gary suffered from a lung problem that was primarily due to his heart problem, or if he had a lung problem that was primarily due to reactive airways disease.

Because of the varying opinions as to the cause of Gary's breathing difficulties, there were also differing views as to how this condition should be treated. McNeill testified that there was a question as to whether or not to increase Gary's diuretics. She said that Giddins was of the view that it would make no major difference to Gary's condition, since the primary problem was significant reactive airways disease.

However, the Pediatric Service did, on occasion treat Gary with extra doses of diuretics as needed to cope with his heart failure. In addition, respirologists had concluded that Gary did not have an acute viral infective process but suggested that something more be done to improve his heart condition, which could be in the form of more or different medication. Odim, Giddins and McNeill also concluded that there was no infection but that Gary's breathing problems could not be addressed until his cardiac problems had been dealt with by surgery. McNeill also testified:

> What I am saying is the respirologist, the cardiologist and myself all believed that his respiratory status was a combination of primary respiratory reactive airways disease, with a contribution from his cardiac condition. (Evidence, page 13,072)

Gary's breathing problems and the doctors' differences of opinion continued right up until surgery. On March 1, Giddins examined Gary and heard wheezing. He noted that Gary's chest X-ray showed over-inflated lungs, with mild enlargement of the heart. He wrote that the X-ray suggested "signs of more chronic respiratory nature than pulmonary edema." (Exhibit 5, page CAR 81)

Pulmonary edema, or fluid in the lungs, occurs when the heart is in failure. In this condition, blood backs up in the lungs and fluid from the blood passes into the tissues of the lungs. Giddins suggested discontinuing the digoxin and then the Lasix, a diuretic. This drug helps the body get rid of excess fluid and treats pulmonary edema. Giddins indicated that the obstructive airways required treatment. He also suggested doing a test to rule out cystic fibrosis, and consulting with the Respirology Service.

On March 2, the digoxin was discontinued, but the Lasix was still given twice a day and sometimes an extra dose was required. The report from the chest X-ray taken that day suggested "the findings may be the result of pulmonary edema." (Exhibit 5, page CAR 109)

On March 3, despite being treated with Ventolin, a bronchodilator, Gary had increased respiratory distress. He had decreased air entry in both lungs, with increased wheezing and took longer than normal when exhaling (a sign of increased respiratory difficulty). He had gained 278 grams in three days and 108 grams overnight. (This rapid weight gain was considered a sign of fluid retention.)

At 1445 hours the senior pediatric service resident wrote, "RSV [Respiratory Syncytial Virus test] negative but may have underlying lung disease (obstructive)." (Exhibit 5, page CAR 49) This assessment suggested that Gary's current respiratory status was likely the result of his heart problems and possibly related to discontinuing the digoxin. At the time, Gary was given an extra dose of Lasix.

Later that day, Dr. Salvador, a cardiology resident, saw Gary and determined that his current respiratory distress was not due to sudden heart failure but was the result of either a respiratory infection or his having had a viral infection. Salvador maintained it was too soon after stopping digoxin (24 hours) for Gary's problem to be heart failure. Salvador suggested that Gary not be given any digoxin that day. He added that if the next day it appeared that heart failure was exacerbating the chest condition, Gary should then be treated with digoxin. The results of a chest X-ray taken that day indicated a slight worsening of the pulmonary edema.

On March 4, Giddins wrote in the chart that there was no need for digoxin and commented that there was certainly significant shunting (from the VSD). Dr. K. Bergen noted that although there was still significant wheezing present that day, a change to another bronchodilator, called vaponephrine, had made a significant improvement in Gary's chest. The antibiotic, which had been started in Lynn Lake, was stopped. During this time Gary also continued to have occasional regurgitation and/or vomiting with coughing spells. The tests for cystic fibrosis and RSV infection were negative.

From then until the evening of March 8, Gary's condition remained relatively stable. However his weight increased 400 grams from March 7 to March 8 and an extra dose of Lasix was given in the morning of March 8. Bergen noted, "Lasix in extra doses have [sic] also been used to decrease wheezing secondary to CHF [congestive heart failure] identified by large increase in weight." (Exhibit 5, page CAR 58)

On March 10, a respirologist examined Gary and found he had wheezing when breathing, along with mild in-drawing. His weight had also increased. The same specialist noted that Gary had respiratory symptoms related to his cardiovascular status, but these symptoms were responding to vaponephrine. He also suggested increasing the diuretics and restarting digoxin. It was noted later that day that Gary had an occasional discharge from his nose.

That same afternoon, McNeill saw Gary in order to conduct an anaesthetic assessment. She noted that he was wheezing. He looked distressed, had flaring of his nostrils and in-drawing. (All of these were signs of difficulty with breathing.) McNeill reviewed Gary's test results and concluded that his borderline congestive heart failure was still not being controlled completely. She questioned whether or not his diuretic therapy should be increased pre-operatively. She suggested that post-operatively Gary would likely have poor ventricular function, with increased pulmonary vascular resistance, and that there was an increased risk of respiratory complications. McNeill also noted that she would reassess his clinical status pre-operatively.

When questioned, she said that she returned to reassess Gary but did not record her findings in the chart. She agreed that she should have done so. She said Gary's condition continued to vary and that no single treatment seemed to be able to correct the situation (Evidence, pages 13,084–13,085).

By that evening, Gary was in moderate respiratory distress, with a fair amount of wheezing. Another dose of Lasix was given, as well as vaponephrine, which improved his air entry.

Wheezing was noted again on March 11 and March 14, along with a large amount of nasal discharge, just before surgery. However, no further tests were conducted to see if Gary had a lung infection. Several expert witnesses commented on the decision to operate without checking further for a lung infection. Cornel stated:

> The cause of the wheezing was not clear and if there was serious concerns that this was an infectious origin I feel that more viral studies were indicated. I believe this baby's respiratory problems placed him in a higher risk group for surgery. (Exhibit 353, page 11)

It is worth noting here that Gary's mother had not been told that there was any increase in his risk level from his respiratory problems.

A pre-operative infection is a source of potential danger for any patient. In its directions to parents of its patients, the Variety Children's Heart Centre specifically warns parents to watch their child for infections and colds before surgery and to advise medical staff of any such problem on admission. The importance of guarding against colds and other infections has to do with the child's ability to deal with the impact of open-heart surgery, particularly on lung function. There is also a concern that a child with an infection could pass that infection on to other children in the PICU.

In his testimony, Cornel stated that it was his practice to postpone surgery in the face of an active viral infection.

> I am concerned that we should not operate if we don't have to when there is a remedial problem in front of us. So a suggestion of a viral infection makes me back off. And a suggestion can be a running nose, a cough, a fever that is unexplained, or a fever at all.
>
> I like all these symptoms to be clear, because if a child seems to have something mild that is going away, we do not know, without a little time, if that's a precursor to a more serious illness that is coming, or the tail end of something that has just gone. Therefore, I will usually postpone surgery if there is any suspicion of an infection. (Evidence, pages 44,688–44,689)

Dr. Robert Hudson[1] said that Gary "was still not in optimal condition at the time of surgery." (Exhibit 307, page 1.13) He said that with appropriate therapy it would have been possible to improve his condition. "Therefore, regardless of the etiology of his respiratory distress, he was taken to the OR without optimal treatment of his cardiac and/or pulmonary problems." (Exhibit 307, page 1.14) He wrote in conclusion that "in my opinion, this patient's cardiorespiratory problems were not optimally treated before surgery. This is a basic standard of care in elective situations." (Exhibit 307, page 1.15)

These experts seemed to be suggesting that as a result of his VSD, Gary was in congestive heart failure, and likely had an underlying infection lurking in his lungs. That infection they felt required treatment, or at the very least, further exploration.

Odim and Giddins, on the other hand, indicated that they were of the view that Gary was not suffering from a chest or any other type of infection at the time of the operation. Giddins pointed to the fact that Gary did not have a fever at any time after his admission until the operation and that elevated temperatures were inevitably present whenever there was an infection. Giddins acknowledged that tests for infection were not ordered before the operation but that such tests were not routinely ordered pre-operatively.

Odim similarly said that he saw no signs of an infection and that he felt Gary was in the best condition they could get him in before the operation. Giddins, as well, thought that Gary was not going to get any better and that the longer they waited, the worse his condition was likely to become.

McNeill testified that after speaking with the respirologists and cardiologists, she was satisfied that they had done the best they could to get Gary in the best possible condition for surgery. She did not believe that anything else could have been done pre-operatively to improve his intra-operative or post-operative cardiac function. She agreed with Giddins's assessment that his cardiac lesion was the key problem contributing to his pre-operative status and to his cardiac problems post-operatively. In her testimony, McNeill said that she did not believe that more aggressive treatment would have made any difference in Gary's condition pre-operatively. When asked if ensuring a child was in optimal condition for surgery was a shared responsibility, McNeill testified:

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[1] Dr. Robert John Hudson is a member of the staff of the Department of Anaesthesia at the University of Manitoba and affiliated with St. Boniface General Hospital. Hudson graduated in medicine from the University of Manitoba Medical School in 1977. He interned and was a resident in anaesthesia from 1978 to 1980. He was a clinical fellow in critical-care medicine at the University of California in San Francisco, and was a research fellow in anaesthesia and clinical pharmacology at Stanford University in Palo Alto, California, from 1981 to 1982. He was certified as a specialist in anaesthesia by the Royal College of Physicians and Surgeons of Canada and by the American Board of Anesthesiology in 1983. He was also certified in echocardiography by the College of Physicians and Surgeons of Manitoba in 1994.

At the time of his evidence, Hudson was a full professor in the Department of Anaesthesia, Faculty of Medicine at the University of Manitoba.

Hudson was acknowledged as having special expertise in anaesthesia and was permitted to give expert evidence to the Pediatric Cardiac Surgery Inquest in that area.

> It's a shared responsibility. Between, well, the anaesthetist and whatever medical person is involved, so in these cases, a cardiologist or respirologist, if there are other consultants involved, and the surgeon also has a responsibility that surgical related issues are controlled or treated or dealt with properly. (Evidence, pages 13,795 – 13,797)

When asked if she were unable to resolve the concerns she had about a child's preoperative condition, whose decision it was as to whether or not to give the anaesthetic, McNeill testified:

> Well, I mean, the bottom line is that if you do not feel that you can—to give an anaesthetic to any child for any reason, medical, social, technical, whatever, it's our final responsibility or our final judgment to withhold the anaesthetic. (Evidence, page 12,930)

In Gary's case, McNeill spoke to both Giddins and the Respirology Service before making her decision to go ahead with the anaesthetic. She testified:

> So having those views expressed to me, I decided that we would go ahead, accept that his lungs were not dry, and we would perhaps have problems peri-operatively with his respiratory function because of that. Also knowing that his cardiac function was not totally normal because of the lesion that he had, and that we may have post-operative difficulties with contractility given his pre-existing, or pre-operative cardiac function, plus what we were going to be doing to him.
>
> So that would be my assessment of going in, that he was at increased risk for both respiratory and cardiac dysfunction post-operatively. (Evidence, pages 13,098 – 13,099)

CONCLUSION AS TO GARY'S PRE-OPERATIVE STATUS

The decision that Giddins made in the fall of 1993 not to operate until it could be determined whether or not Gary's VSD would close on its own was a reasonable one. Additionally, given Gary's condition at the time of his initial diagnosis, delaying surgery in order to see if his size and strength could be improved through appropriate medical attention was also a reasonable plan.

There is insufficient information on the record to determine if the medical authorities in Lynn Lake were sufficiently attentive to Gary's development. However, it does seem clear that Gary did not gain much size or strength between the time of his initial diagnosis and his next Heart Centre visit. Giddins and Odim concluded that Gary was not going to gain any more strength or size, due in part, at least, to the fact that his cardiac condition had deteriorated to the point where it was interfering with that development. That also seems to be a reasonable conclusion.

There is a difference of opinion between those who participated in Gary's treatment and those who reviewed the case for the Inquest, as to whether or not the operation should have been delayed in order to treat Gary for his lung condition. While Giddins and Odim discounted the possibility of an infection, they did not order appropriate tests to determine if one was present or not.

The possibility of an increased risk to Gary because of his respiratory problems was not discussed with his parents before the operation, although there was opportunity to do so.

THE OPERATION – MARCH 14

Gary was taken to the operating room at 1215 hours on March 14, 1994. The members of the surgical team are set out in the accompanying chart.

TABLE 6.1: Persons involved in the operation on Gary Caribou, March 14, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	B.J. Hancock
Anaesthetists	A. McNeill, H. Grocott (resident)
Anaesthetic nurse	I. Hinam
Scrub nurses	C. Youngson, C. McGilton
Circulating nurses	B. Ziemski, S. Scott, K. Steindl, A. Glenday
Perfusionists	M. Maas, T. Koga

TABLE 6.2: Length of phases of the operation on Gary Caribou, March 14, 1994

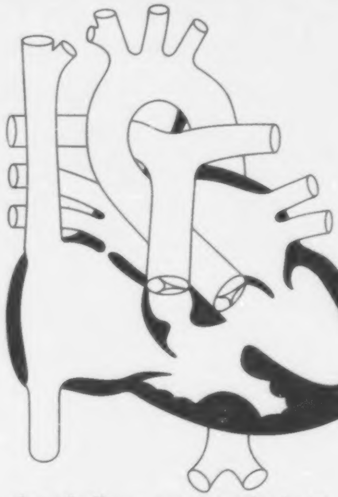
Phase of the operation	*Time taken*
Induction	1 hour 44 minutes
Bypass	3 hours 46 minutes
Aortic cross-clamp	1 hour 39 minutes
Total surgical time	7 hours 41 minutes
Total operating-room time	9 hours 40 minutes

Induction took one hour and forty-four minutes. This was a lengthy time, although there was no evidence to suggest that this contributed to or caused any deterioration in Gary's health. However, the length of induction time in Winnipeg was to become a matter of conflict between Odim and the anaesthetists.

It was difficult to discern from the information on the 1994 perfusion records as to when and how much cardioplegia was given per dose and at what temperature. In his report to this Inquest, Cornel expressed concern about the adequacy of myocardial protection during CPB, since no details of the cardioplegia technique were available.

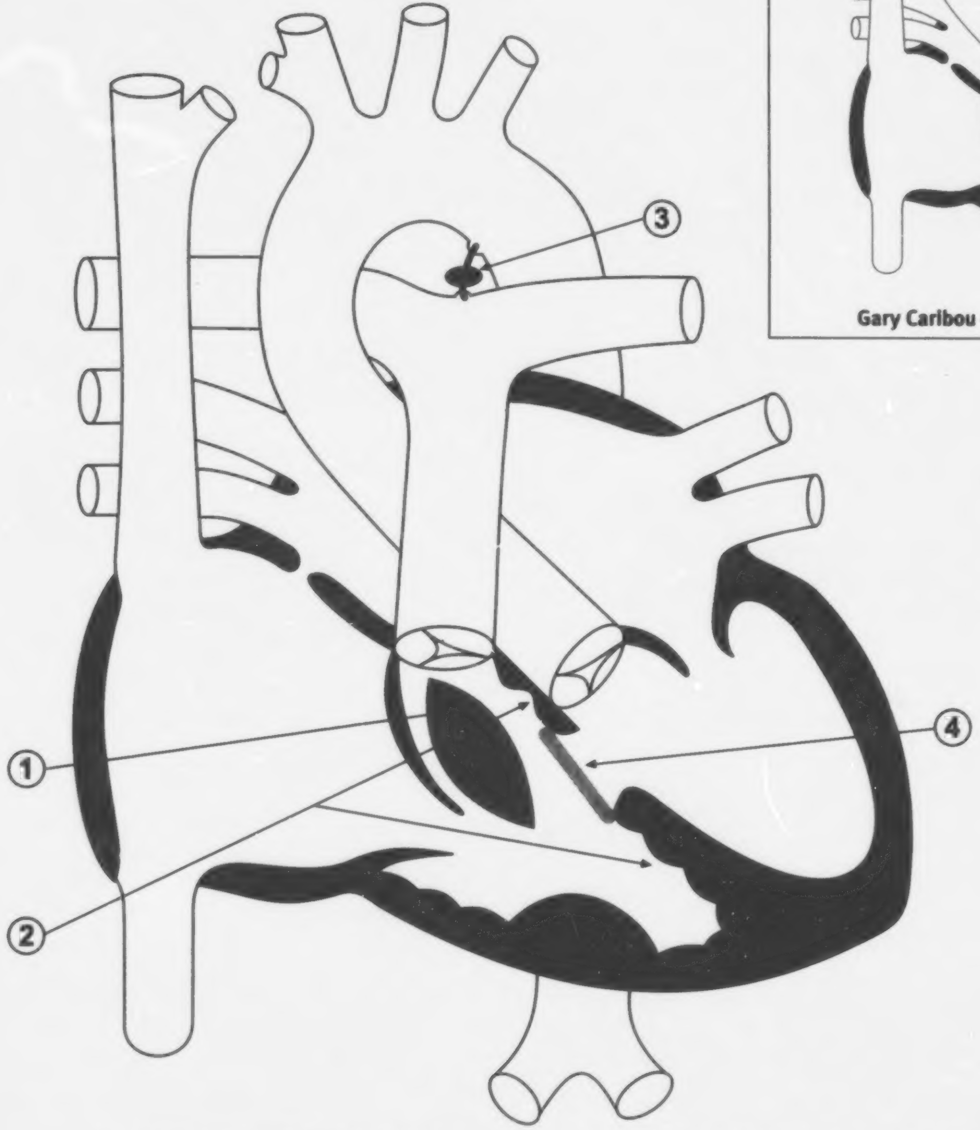
Cardioplegia is the combination of chemicals and cold solution administered to the heart to stop it from beating and to protect it during a cardiac procedure. The administration of cardioplegia is a matter largely controlled by the surgeon, who decides how and when cardioplegia is administered, but the cardioplegia is actually administered by the perfusionists through the lines connected to the CPB machine.

As events of 1994 unfolded, it became apparent that sometimes, one large dose of cardioplegia might be administered during a case (and might be considered sufficient). At other times, cardioplegia might be administered at the outset of a procedure and then, periodically while the procedure continued, further smaller doses might also be administered.



Gary Caribou – pre-operative heart

Diagram 6.2 Gary Caribou – post-operative heart



1 – Pericardium patch on right ventricular outflow tract obstruction with resection of muscle bundles

2 – Muscle bundles have been removed or resected from these areas

3 – Ligation of ligamentum arteriosus (former ductus arteriosus)

4 – Patch closure of ventricular septal defect

The record of how and when cardioplegia was administered in this and other cases was maintained by the perfusionists. However, during 1994 the perfusionists simply recorded the total amounts of cardioplegia given and not if it was administered at different times and doses.

Subsequent to these events, a new record-keeping technique has been put in place whereby each dose is recorded separately. It is this latter information that Cornel was unable to determine from the chart and which he felt was of some importance.

The evidence from the perfusionists and from the surgeon was to the effect that they felt that the administration of cardioplegia in this case was adequate to protect the heart. While Cornel's concerns are valid, they point more to a problem with record-keeping than to a problem with cardiac protection in this case. In some of the later cases, however, there is reason to feel that, based on the information available as to how cardioplegia was administered, cardiac protection may not have been adequate. It would not be reasonable to suggest the same in this case, however.

The operation involved repairing the ventricular septal defect with an artificial patch made of Dacron, patching the right ventricular outflow tract with Gary's own pericardium (tissue taken from the sac surrounding the heart), cutting out the muscle bundles from the right ventricle and, according to Odim's notes, tying off the ductus arteriosus. (Given Gary's age and the fact that no PDA was diagnosed, it is likely this was a ligamentum arteriosus.) The muscle bundles in the right ventricle initially obscured Odim's vision of the VSD. For this reason he decided to gain access to the defect through the outlet tract of the right ventricle. He placed sutures around the VSD. A Dacron patch was then secured to each pair of sutures, seating the patch over the hole. Once the patch was put in place, Odim examined the patent foramen ovale and chose not to close it. At that point the team began the process of preparing to go off bypass.

Odim was questioned on the duration of the operation and the bypass time in particular, both of which were considered to be lengthy. He said that:

> there were factors that contributed to the bypass time, and potentially factors that could improve on those times. But after sort of reviewing the types of bypass times for this procedure in Winnipeg over the last eight years, I was not impressed with the fact that this time was appreciably more significant than other bypass times in our system. (Evidence, page 24,104)

He acknowledged that the times would have been shorter in Boston or Montreal, but noted that in those locations there would have been three surgeons involved in the operation. He did not believe the operation had been particularly difficult, but he did state that:

> It was certainly longer in the initial period, because I was working with people who, and they were working with me, who didn't know techniques or were used to other techniques in the past. And clearly there is a lot of explanation, a lot of this is what I want you to do and that type of thing going on to get the job done. So my feeling was that these types of things would improve with time, as you worked with the personnel. (Evidence, pages 24,105–24,106)

This was one of Odim's early operations in a new setting, a fact that likely contributed to the length of time of the operation. Additionally, Odim's use of interrupted sutures when attaching patches to the heart might also have lengthened the operation. This suturing technique, known as using a pledgetted mattress suture (using many separate sutures), is quite acceptable but can lead to extra time being taken while the patient is on bypass. The alternative, a running suture (or continuous suture), can be put in more quickly, but is less secure.

In her testimony, Youngson said that she believed Odim's suture technique added to the length of the operation:

> I remember that it was a struggle, it was difficult, especially in such a little person, a little baby, to have so many sutures in the field. They seemed to be getting tangled from time to time and it was just difficult. (Evidence, page 8,374)

Gary experienced several problems during the course of surgery. The first occurred at 1440 hours, when there was an episode of supraventricular tachycardia (a type of abnormal heart beat or arrhythmia in which the heart beats very quickly). This resulted in a severe drop in blood pressure, just before going on bypass at 1455 hours. The tachycardia was successfully treated by cardioversion (or the application of a mild electrical shock). In his report, Hudson suggested it was common for arrhythmias to occur during manipulation or cannulation of the heart. Gary's oxygen saturation was above sixty per cent during bypass until 1645 hours, when the measurement began falling. The saturation declined to 24 per cent at 1815 hours and then began climbing again.

Throughout the procedure, the team was concerned about Gary's low oxygen saturation. However, once he came off bypass and was treated with a drug used to raise blood pressure, his heart was in a normal rhythm. Odim said he was never able to reach a satisfactory conclusion as to why Gary had experienced such low levels of saturation during the operation.

Gary's chest was initially closed in the operating room. Following this, his blood pressure suddenly decreased at 2045 hours. As a result Odim decided to reopen the chest. When he did so, the chest was found to be oozing blood (a sign of coagulopathy—a clotting problem leading to bleeding). This required treatment with a variety of blood products. In his operative report, Odim wrote, "Hemostasis [stopping of bleeding] was difficult to achieve because of ongoing coagulopathy and we therefore decided to delay sternal closure." (Exhibit 5, page CAR 91)

Delayed sternal closure simply means that Odim decided not to close Gary's chest but to let it remain 'open'—but covered with a silastic membrane (a silicone rubber dressing) in order to prevent infection—while Gary recovered from the operation. This technique is one that is often necessitated by the fact that the heart and the area of the chest where the operation is performed can become swollen as a result of surgery, to the point where closing the chest can impair heart performance. Many things can contribute to swollen heart and chest tissues, including inadequate cardiac protection or the length of the procedure. Odim's operations during 1994 were generally longer than what one would normally expect. ICU staff commented that they perceived that more of his patients with delayed sternal closure had to be reopened in the ICU than they had previously experienced. Gary was transferred to the PICU with a silastic dressing covering his chest.

POST-OPERATIVE COURSE

Gary was transferred to the PICU at 2155 hours.

Within forty minutes of his arrival in the PICU, Gary's blood pressure suddenly dropped. He was rapidly given blood products and calcium. Despite this treatment, his condition deteriorated and he had a cardiac arrest at 2242 hours. He was successfully resuscitated with internal cardiac massage, epinephrine and lidocaine.

Gary remained in critical condition, with low blood pressure and high pulmonary pressure. He required the continuous administration of drugs to maintain a stable blood pressure during his entire stay in the unit. He suffered two additional cardiac arrests during the night, both of which required treatment with open cardiac massage and the administration of multiple bolus injections of blood products.

Early in the morning of March 15 Odim decided to close Gary's chest. This created considerable consternation for the PICU nursing staff. According to Feser, closing a chest is generally considered to be an OR procedure at the HSC. She was asked if the PICU staff had been trained to assist with this procedure.

> No, they are not. They are not something that we are trained in or trained for. We are not OR trained nurses, we are not trained in OR setups, how to handle things in that respect. (Evidence, page 29,850)

Feser said she was "flabbergasted" by the development. She felt that the PICU nurses had not been given the proper notification that this procedure would be undertaken. She said that in the past Duncan would have provided notification for far less significant procedures. She also said that the PICU was not properly equipped to reopen or close a patient's chest. At the time, Feser told Odim that the normal procedure was to send a patient to the OR and have an anaesthetist present when the chest was being closed. Despite her concerns, Odim proceeded to close Gary's chest, with the assistance of PICU staff. An anaesthetist was not asked to attend.

Nitric oxide was administered at 0920 hours, with no effect on Gary's pulmonary pressures. The PICU resident noted that Gary had decreased blood pressure, decreased kidney function, decreased liver function and a coagulopathy. A chest X-ray report stated, "There is a further increase in pulmonary density on both sides, most likely the result of a combination of edema and pneumonia, although a significant atelectasis [or collapse of lung tissue] might also be present." (Exhibit 5, page CAR 113)

Later that day, after concluding that Gary was suffering from acute kidney failure and fluid overload, the PICU doctors consulted the Nephrology Service. The nephrology consultant decided to drain some of the fluid in Gary's abdominal area by performing a procedure called peritoneal dialysis. This is the term used to describe a form of dialysis (or artificial kidney function) in which the patient's own abdominal (or peritoneal) cavity is used as the container for the dialysis fluid. The actual procedure involves inserting a catheter into the abdominal cavity and draining off any fluid that might have accumulated there (termed ascitic fluid or ascites). The abdominal cavity is then filled with the dialysis fluid, which cleans the blood of waste products through contact with adjacent blood vessels. After allowing time for the waste products (normally removed by the kidneys) to move into this fluid, the dialysis fluid is then drained out, taking the wastes with it.

The procedure began at approximately 2020 hours, and was carried out by Dr. Paul Grimm, a nephrologist, and his assistant, Dr. Birk. Two hundred and forty millilitres of peritoneal fluid was removed from the abdominal cavity. While the procedure was taking place, however, Gary suffered a significant episode of hypotension (low blood pressure), and his condition quickly deteriorated to the point where the doctors started external massage of his heart. He died at 2209 hours.

AUTOPSY FINDINGS

Despite the policy of the Chief Medical Examiner to hold autopsies in all pediatric intra-operative deaths, an autopsy was not held because Gary's family objected. Charlotte Caribou testified that she withheld her consent because she felt that "they cut him up enough." (Evidence, page 1,955) Her wishes were respected.

It is hard to disagree with the Chief Medical Examiner's decision to respect the wishes of the mother of the dead child. The Chief Medical Examiner, Dr. Peter Markestyn, testified that wishes of the family would be respected if sufficient information as to the cause of death was otherwise available and the attending doctor was prepared to certify the cause of death. In Gary's case, Odim had indicated to the CME's office that he was prepared to certify Gary's cause of death. He wrote that Gary died of cardiac failure (Exhibit 5, page CAR 14).

FINDINGS

As noted at the outset, this case gave rise to the following questions:

- Was there an inappropriate delay between the time of Gary's diagnosis and the date of the operation on his heart?
- Was his mother provided with sufficient information to allow her to give informed consent to the procedure?
- Was Gary healthy enough to undergo an operation?
- Did the length of surgery contribute to his death?
- Did the post-operative abdominal drainage procedure contribute to his death?
- What was the cause of death and was it preventable?

Was there an inappropriate delay between the time of Gary's diagnosis and the date of the operation on his heart?

One of the reasons for Gary's death advanced by the consultants engaged to review this case for the Inquest was his weakness at the time of operation. A question therefore arises over the wisdom of not performing surgery in December 1993, when the condition was first diagnosed. Although there was no surgeon available in Winnipeg to perform the operation, arrangements could have been made for Gary to be sent to another heart program in another province.

Giddins testified that experience had shown that in young children, small holes in the heart could close on their own, without any surgical intervention. At the time, Giddins was unable to come to a conclusion as to whether or not surgery was required or if Gary's defect might heal on its own. Giddins believed that the possibility of the holes closing on their own was preferable to surgery, particularly in light of Gary's already frail condition. As well, Giddins thought that Gary's overall condition could be improved with medical assistance.

- **Finding**

  Allowing a septal defect to heal on its own is a better course than closing it surgically. Surgery has many pitfalls, including a certain degree of risk—albeit sometimes small—of a fatal outcome. Giddins's decision to wait to see if the defect in the septum would close on its own was a sensible medical decision.

Was Gary's mother provided with sufficient information to allow her to give informed consent to the procedure?

- Finding

No one told Charlotte Caribou that the surgeon had never before performed this type of surgery on this type of patient without supervision. She was unaware of the fact that the surgical team had performed only a very few simple operations together. Additionally, she was never told that her son's chest condition placed him at increased risk for the procedure he was undergoing.

All of this clearly might have influenced a reasonable person in her decision when giving consent to this operation being performed by this surgeon in this setting and therefore, should have been shared with her. The fact that this information was not shared tends to suggest that Gary's mother was not provided with sufficient information to allow her to give informed consent to the procedure.

Was Gary healthy enough to undergo an operation?

Several of the consulting witnesses who testified laid considerable stress on Gary's pre-operative condition. Cornel wrote: "The possibility of an important contribution to the demise by an intercurrent [ongoing] viral illness cannot be ruled out." (Exhibit 353, page 12) Dr. Walter Duncan[2] concluded that Gary had experienced severe heart failure pre-operatively and died of lack of blood flow or low cardiac output post-operatively.

- Finding

There is some evidence to suggest that Gary might have had a chest condition at the time that the operation was scheduled. While some significant features of an infection may not have been present (notably a fever), the evidence suggests that the surgeon and the cardiologist did not gather enough information to completely discount the existence of an infection.

Because of the tremendous importance that has been placed on the impact of infections on the recovery of pediatric cardiac patients, and the valid concerns raised about this issue by the consulting witnesses, Drs Giddins, Odim and McNeill should have ensured that proper tests were conducted to exclude the possibility of a chest infection before proceeding with the operation.

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[2] Dr. Walter J. Duncan was, at the time of his testimony, a member of the staff of the Department of Pediatrics at the British Columbia Children's Hospital. A 1974 graduate of the College of Medicine at the University of Saskatchewan, Duncan interned at St. Paul's Hospital in 1975. From 1975 to 1982, he was at the Hospital for Sick Children in Toronto: as a resident in pediatrics (1975–1977), resident in pediatric cardiology (1977–1978), and clinical fellow in cardiology (1978–1979). He was certified as a fellow of the Royal College of Physicians and Surgeons of Canada in pediatrics. He was certified in general pediatrics by the American Board of Pediatrics in 1980, and was also certified by the Royal College of Physicians and Surgeons of Canada in pediatric cardiology in 1981. He held the positions of assistant professor of pediatric cardiology and pediatrics (July 1979 to June 1982) at the University of Toronto and was the section head of echocardiography during that time at the Hospital for Sick Children.

In 1982 he was appointed associate professor and then professor in 1988 in the Department of Pediatrics, Faculty of Medicine, University of Saskatchewan. He then was appointed professor in the Department of Pediatrics at the University of Ottawa and chief of the Division of Cardiology at Children's Hospital of Eastern Ontario.

In 1998 he was appointed to the Department of Pediatrics at the University of British Columbia and joined the staff of the British Columbia Children's Hospital.

He was acknowledged as having special expertise in pediatric cardiology and was permitted to give evidence to the Inquest in that area.

Did the length of surgery contribute to his death?

Considerable weight was also placed on the damage that was done to Gary by the length of the procedure.

Hudson wrote that:

> … the need to leave the chest open because the patient cannot tolerate the hemodynamic effects of sternal closure is also more common after unduly prolonged CPB. Such severe cardiac failure in the early post CPB period suggests that there was significant myocardial injury during CPB. (Exhibit 307, page 114)

In their joint report, Cornel and Duncan stated that:

> The etiology of the demise of this child remains uncertain. Contributing factors may have been an abnormal coagulation status, abnormal lung function and a relatively long surgical procedure. (Exhibit 354, page 2)

Dr. Christian Soder[3] indicated in his report for this Inquest that:

> **The skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations. Surgical factors were the prime determinants of fatal outcome in 9 of the 12 deaths.** (Boldface in original) (Exhibit 345, page 8)

The case of Gary Caribou was one of the nine that Soder identified in which surgical factors were a prime determinant in a fatal outcome. In particular, he identified the lengthy bypass and cross-clamp time, and the excessive bleeding.

■ Finding

While a clear cause of death cannot firmly be established, it appears from the available evidence that the child was in a significantly compromised state when he entered the operating room, and the length of the operation seems to have been a significant contributing factor in his death. The evidence suggests that the length of the operation appears to have been directly related to the ability and inexperience of the surgeon.

Did a post-operative abdominal drainage procedure contribute to his death?

During the course of this Inquest, questions were raised about the peritoneal dialysis. The wisdom of the rapid drainage of a large volume of peritoneal or ascitic fluid was questioned by Cornel. In his view, given

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[3] Dr. Christian Max Soder was born in Switzerland and graduated from the University of Alberta Medical School in 1975. He interned at the University of Alberta Hospital in 1976 in pediatrics, and was a resident in pediatrics in 1977. He took a position as resident in anaesthesia at the University of Toronto in 1977 and in 1978 was a resident in anaesthesia at the Toronto Hospital for Sick Children. In 1979 he became a fellow in pediatric intensive care at the Hospital for Sick Children and in 1980 was a resident in internal medicine at the Toronto General Hospital and a chief resident in anaesthesia at St. Michael's Hospital in Toronto.

A fellow of the Royal College of Physicians of Canada, he received a specialist certificate in pediatrics in May 1980 and a specialist certificate in anaesthesia in September 1980.

At the time of giving his evidence, Soder was on the full-time medical staff of Isaac Walton Killam Children's Hospital in Halifax, Nova Scotia, was an associate professor in the Department of Anaesthesia at Dalhousie University, a lecturer in the Department of Pediatrics at Dalhousie and chief of the Department of Anaesthesia at Isaac Walton Killam Grace Health Centre. He was also the director of intensive care at Isaac Walton Killam Grace and the medical director of the STARS NS (Shock Trauma Air Rescue Society) in Nova Scotia. He was a medical adviser as well with the Department of Respiratory Therapy at Isaac Walton Killam Grace. His publication and presentation list was extensive. Soder was permitted to give expert evidence with respect to anaesthetic and intensive-care issues that arose in a review of the cases before the Pediatric Cardiac Surgery Inquest.

Gary's fragile state, any significant change in blood pressures would be difficult for Gary to cope with. In his written evidence, Cornel stated: "Rapid drainage of a large volume of ascitic fluid following the insertion of peritoneal dialysis catheter was associated with the final demise of the infant." (Exhibit 353, page 12)

The dialysis procedure involved draining ascitic fluid, injecting dialysis fluid into Gary's abdominal cavity, and then draining the dialysis fluid to relieve pressures and remove impurities. What was most important during the procedure was to ensure that there was close monitoring of any changes in pressure in the abdomen (from the fluid) on the function of the heart. This would appear as changes in heart rate and blood pressure. For example, a sudden increase or decrease in fluid pressure in the abdomen could produce a decrease in blood flow to the internal organs and to the heart itself. Thus, the key to the procedure was to ensure that flow of fluid into or out of the abdomen occurred at a rate that the heart could handle.

In many other facilities, including the Children's Hospital of Eastern Ontario where Cornel is the chief of pediatric cardiac surgery, a surgeon carries out the dialysis procedure on post-cardiac surgery patients, with the assistance of a nephrologist. In particular, Cornel said, it was important to limit the volume of liquid used and the rate at which it was drained.

Grimm testified that this was a procedure that he had performed many times previously and that in Gary's case he had followed all of the usual procedures. Grimm was assisted by Birk and by at least one PICU nurse. Neither Odim nor Hancock, (the intensivist on duty that evening) nor Dr. Ellsabete Doyle, the PICU resident, were present during the procedure.

Grimm was of the view that nothing done in the course of the dialysis procedure was a factor in Gary's death. He rejected any suggestion that the removal of fluid was conducted too quickly, pointing to the fact that while the initial fluid was being removed, Gary's blood pressure did not change, and there was no adverse reaction to the insertion of the catheter. He pointed out that the initial volume of dialysis fluid had been inserted and removed without incident as well, and that the second volume was in Gary's abdomen when Gary began to deteriorate. However, Grimm did not disagree with Cornel's view about the need to proceed slowly in the removal and replacement of fluids in this type of procedure.

- **Finding**

It would appear that nothing Grimm did during the dialysis procedure was inappropriate. It is uncertain as to whether or not the dialysis procedure caused such a sudden change in Gary's blood pressure from which he was unable to recover. However, it would have been desirable for Odim or one of the intensivists to have been present while this procedure was being undertaken.

What was the cause of death and was it preventable?

It is unfortunate that an autopsy was not held. It will remain unclear if the medical issues that were part of Gary's demise could have been better determined. Coming to a conclusion as to exactly why Gary died will remain speculative, although there is sufficient information to reach some solid conclusions.

- **Findings**

There is no suggestion that the surgical repair of the VSD was not successful. Although an autopsy was not performed, the available evidence suggests that the VSD was successfully patched.

However, the operation appears to have taken too long. The evidence suggests that the lengthy bypass and cross-clamp times may have significantly compromised the baby's chances of recovery. There seems to have been little more that could have been done for the baby post-operatively than was done in this case.

For these reasons, the evidence suggests that this death was possibly preventable.

POST-MORTEM ISSUES

After this case, Feser spoke with Dr. Murray Kesselman, the head of the PICU, to express her unhappiness with the fact that Gary's chest was closed in the unit. Kesselman testified that after speaking with Odim, he concluded that such closures were appropriate in the unit. In some cases, however, patients were taken back to the operating room in order to have their chests closed with the assistance of an OR team.

Feser, along with Borton and Jannell Plouffe, arranged to meet with Odim on March 22, one week after the operation. Feser felt that she needed more information from Odim about how cases would be managed post-operatively. The Caribou case had led her to believe she needed much more information than Odim had provided at their previous meeting. For the March 22 meeting, Feser and her staff had prepared a detailed list of issues that they wanted information about. Feser testified that at this meeting she also reviewed with Odim the PICU policies on the writing of medical orders. She said Odim agreed to provide a list of items to be placed in what was referred to as a cardiac bin. The bin would store the equipment needed for procedures Odim intended to perform in the PICU. Odim did not provide such a list until the end of April. On May 6, the bin was in place. However, in the intervening period, a number of very significant events had taken place, particularly the death of another child (Jessica Ulimaumi) in the PICU.

Feser testified that at the meeting on March 22, she and her staff raised a number of other concerns. She said that the PICU nurses were having difficulty with Odim's request that they call him at 0600 hours to update him on what sort of night his patient had experienced. While she recognized the benefit to the surgeon, she said the unit did not have the resources to carry this out at that time of day.

According to Feser's testimony, another issue that was discussed at this meeting was the prescribing of medications, and particularly pain relief, to patients in the PICU. Odim wished to prescribe what are referred to as bolus doses, which are given intermittently. The practice in the PICU was to use a continuous infusion. This difference later arose as a point of conflict between Odim and other doctors in the PICU. At that time, Feser said she made it clear to Odim that while he could make his preference known, the decision about medication was made by the attending intensivist. This was because the PICU was a closed ward. At the meeting, it was decided that a standard order form would be set up for Odim to use at the end of an operation. According to Feser, Odim was to:

> ... fill it out, but our physicians would still review it and they would still be responsible for writing orders. So they would take off of this sheet what was applicable, what we were going to use, but still write, doctors would still write their own orders post-op. (Evidence, page 29,910)

Feser also raised concerns about the types of monitoring lines that Odim used. Monitoring lines (also called intracardiac lines) are tiny tubes connected to the heart, which pass through the chest wall and are connected to monitoring devices. They are important as a means for staff to observe cardiac performance.

Normally, such lines come in one piece from a manufacturer with a connector at one end. The end without a connector is passed through the chest wall and inserted into the heart or into a blood vessel attached to the heart. The connector is then used to connect the line to a measuring device. Odim's method of insertion involved disassembling the lines.

Feser testified:

> We raised a couple of concerns in doing this. I mean, there is a risk obviously – not obviously, it may be not obvious to people, but it was obvious to me from previous experience that when these lines came apart there was a risk for bleeding, there was a risk for infection. (Evidence, pages 29,902–29,903)

Reimer described the problem:

> If I can describe briefly the way these are inserted, generally they are, the lines themselves are a long piece of tubing and then on the end of them is a connecter called a [Luer] lock connecter which is a sort of locking-type connecter that allows it to be connected with other lines or with monitoring devices and so on.
>
> However, the way they were inserted is they were inserted sort of from inside out. That is, they were placed in the cardiac chamber first, and then they had to be brought through the skin so they could be used. It's not possible to bring a connecter up through the skin, or the connector that is on the catheter.
>
> What Dr. Odim would do is cut the connecter off so he could get it through the chest wall and through the skin, and then he would suture another type of—another piece of tubing with a built-in connecter and he would sort of telescope the two together and tie a suture around them to secure them and that's what he would use.
>
> One of the problems that was being expressed, and this was actually more of an ICU issue than an intra-operative issue, is that these lines were coming apart right at that connection. (Evidence, pages 19,341–19,342)

Reimer said that Duncan had approached the issue differently and in a manner that did not require that the connector be cut off. Because the tube had to pass through the skin and the chest wall, it had to be inserted into the end of a large needle and the needle then pulled the line through the chest wall in a manner that allowed the line to remain intact. Duncan had worked from the inside out, passing the needle from inside the chest to the outside, inserting the tubing into the needle and then pulling it back through the chest wall. He then connected the end of the line to the chest.

Feser testified that Odim said that the lines he used were what he was accustomed to using in Boston and that he found them to be quicker and more efficient to use. This issue would recur during the rest of the year.

Reimer said that because the problem of the intracardiac lines coming apart was a recurring one, he had proposed a solution to Odim.

> The suggestion I made to him is that there is a particular type of epidural catheter that we use in anaesthesia, where we have a similar issue, and that the catheter can't be inserted with a connecter already on it.
>
> So, the way that it is designed is that there is a connecter that can be attached after the catheter is inserted, and it's got—it's designed in such a fashion that it will be secure when the connecter is put on after insertion.

> I showed him this, and I suggested this is something that he might want to try.
>
> *Q.* Did you actually show him the equipment?
>
> *A.* Yes.
>
> *Q.* Did you demonstrate sort of how the equipment worked?
>
> *A.* I'm not sure I took it out of the package, but I certainly showed him all the parts and how it worked.
>
> *Q.* All right. What was his reaction when you showed him this equipment?
>
> *A.* I mean he looked at it, and—but ultimately said that he didn't think he was having a real problem with what he was using at present and didn't see a need to change. And he was also concerned about the expense of the epidural catheters. (Evidence, pages 19,342–19,343)

According to Reimer, catheters cost between two and three dollars. He testified that Odim did not believe that his method was creating any problems and continued to employ it throughout 1994.

THE CASE OF VINAY GOYAL — HIS FIRST OPERATION

ISSUES

Vinay Goyal died on April 18, 1994, after undergoing two operations in the spring of 1994 (one on March 17 and one on April 18) and after experiencing a lengthy stay in the PICU. His case gives rise to the following issues:

- Were Vinay's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Would Vinay have been taken to surgery with a potential infection if his parents had not intervened?
- Did the surgeon demonstrate the skills and experience necessary to undertake this high-risk surgery?
- What was the cause of death and was it preventable?

This case will be discussed in two sections. The first section deals with events leading up to the first operation. The second section (which is separated from the first by a discussion of the case of Jessica Ulimaumi) deals with the second operation. The findings are placed at the end of the second section.

BACKGROUND AND DIAGNOSIS

Vinay Goyal was born March 2, 1990, in St. Boniface Hospital, to Vipan and Sheena Goyal. He was diagnosed at birth with a number of heart defects, including Tetralogy of Fallot. He also had Trisomy-21 or Down's syndrome. After 16 days in hospital, he was discharged home on no specific treatment or medication.

On Monday, June 4, 1990, Vinay was seen in the cardiology clinic at the Winnipeg VCHC. He was breathing rapidly, and his mother reported that his lips were blue when feeding. When seen again on November 12, 1990, following his family's return from India, Vinay appeared deeply cyanosed. He also had clubbing of his fingers. (Clubbing occurs in the fingers and toes of some patients with heart or lung diseases. The tips of the fingers and toes become bulbous and swollen, giving them a 'club-like' appearance.)

An echocardiogram showed:

- a ventricular septal defect
- right ventricular hypertrophy
- significant subvalvular muscular obstruction (This meant that the passageway to the pulmonary valve was obstructed by a build-up of muscle.)
- a small pulmonary valve with a degree of supra-pulmonary valve narrowing (This means that the pulmonary artery was slightly narrowed above the valve.)

In addition, his main pulmonary artery and subsequent pulmonary artery branches were small and underdeveloped.

It was determined that Vinay was in urgent need of surgery.

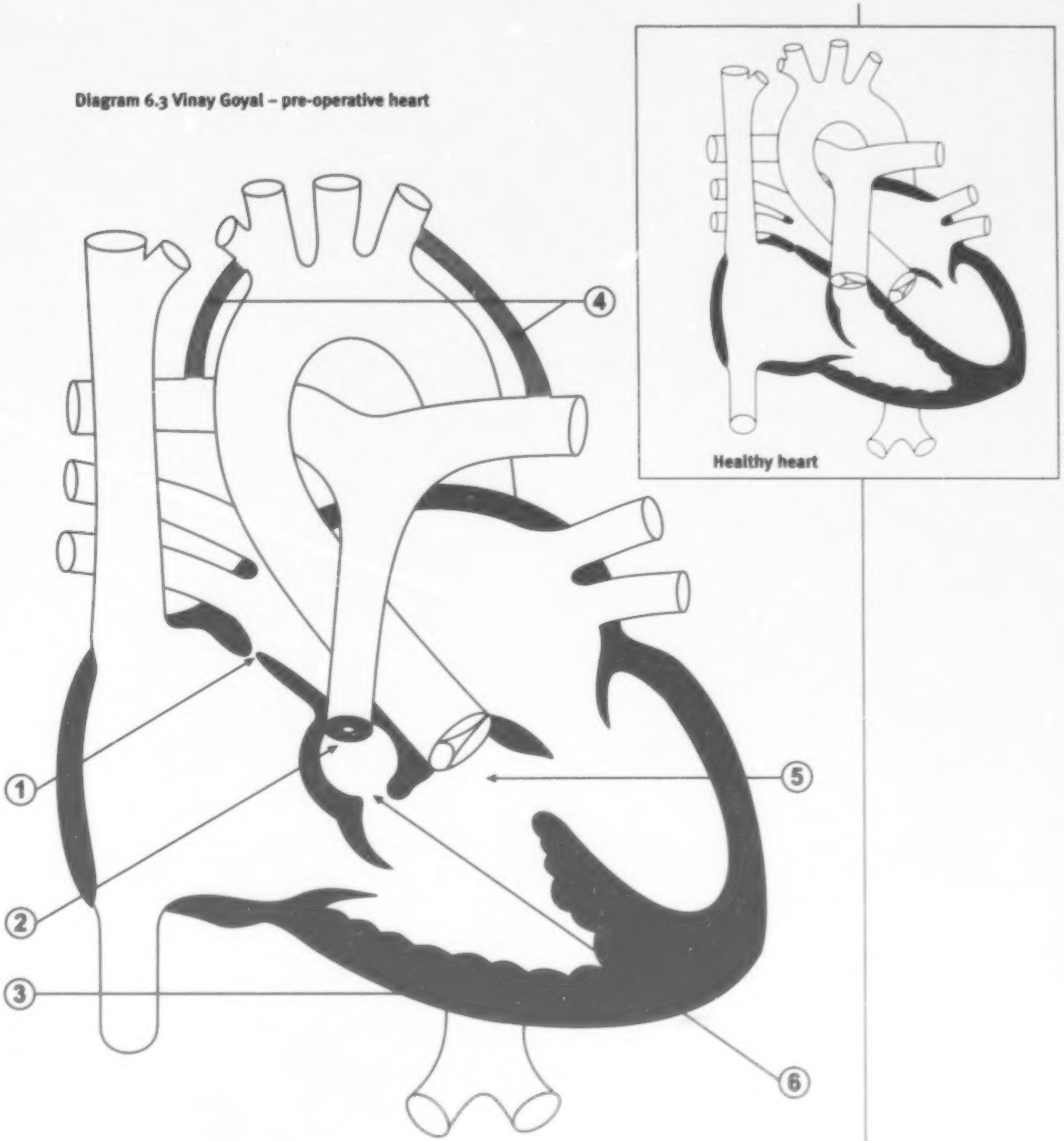
On his November 12 clinic visit, a significant upper respiratory infection was noted. However, surgery was planned for November 26, with the provision that the infection had cleared by that date. Evidently the infection cleared and on November 26, Dr. Kim Duncan placed a Blalock-Taussig (B-T) shunt in Vinay's heart to assist his heart function. Then, when Vinay was 27 months of age, the first B-T shunt was replaced by a second, larger shunt. The first shunt had been originally scheduled for replacement in June 1992 but the operation had been cancelled to allow investigation of another condition – thrombocytopenia (or a decrease in the number of platelets in the blood).

On July 14, 1992, Dr. Rachel Yanofsky, a hematologist, determined that Vinay had compensatory polycythemia with secondary thrombocytopenia. This condition meant that Vinay had an increase in the number of red blood cells, probably because his heart condition made him cyanotic or lacking in oxygen, so his body produced more red cells to carry more oxygen. As a result of the increase in the number of red blood cells, Vinay appeared to have a reduced number of platelets, but this was because the platelets were actually diluted by the increased number of red blood cells. Yanofsky advised that the operation could go ahead and Vinay could be transfused with platelets if necessary. There were no bleeding problems during the second shunt operation on July 16, 1992.

The long-term medical plan was to undertake a more definitive repair when Vinay was older. As he grew, his increasing cyanosis and decreasing exercise tolerance indicated that a total correction was required. By the fall of 1993, Vinay was clearly cyanotic and clubbed. An October 27, 1993, catheterization showed a Tetralogy-type double outlet right ventricle, nearly complete pulmonary valve atresia with subpulmonary muscular obstruction, and a 14 millimetre non-restrictive subaortic VSD. (A subaortic VSD is a VSD that is found just below the aorta in the septal wall.)

In a November 9, 1993, letter to Dr. W. Robinson, the Goyals' family doctor, Giddins wrote, "There are no surprises at catheterization, and I believe his anatomy is suitable for definitive repair in the new year (a decision has been made regarding a surgeon who is to start in January)." (Exhibit 7, page GOY 585) At that point Giddins discussed the need for surgery with the Goyals.

Diagram 6.3 Vinay Goyal – pre-operative heart



1 – Patent foramen ovale
2 – Nearly atretic (or small) pulmonary valve
3 – Right ventricular hypertrophy
4 – Blalock-Taussig shunts
5 – Ventricular septal defect (with overriding aorta)
6 – Right ventricular outflow tract obstruction (Subvalvular muscular obstruction)

THE DECISION TO OPERATE

In their testimony, the Goyals exhibited a clear understanding of the medical problems that their child faced. The nature of the repair seems to have been explained to them as fully as possible under the circumstances. In the fall of 1993 they were told that because there was no surgeon in Winnipeg, the operation would have to take place in either Saskatoon or Toronto. The Goyals' recollections of what took place next differ slightly. Vipan Goyal said that the family had opted for an operation in Toronto. Sheena Goyal said the family never reached a final decision. However, the Goyals said that by December they had been contacted by the HSC with the news that a new surgeon had been hired and it would be possible to perform the operation in Winnipeg.

According to the November letter from Giddins to Robinson, Giddins had intended to send Vinay's medical information to Saskatoon when he received word that a new surgeon would be arriving in January 1994. He also indicated that the VCHC nurses had advised the family of this fact. Giddins informed Robinson that he would be arranging for the case to be done in Winnipeg by the new surgeon since, Giddins believed, the family did not want to go out of the province anyway. In her testimony, Borton said the Goyals had been worried about the financial expenses involved in out-of-province surgery.

A February 2, 1994, VCHC checkup revealed no change in Vinay's condition since the previous fall. Giddins, in a letter to Robinson, stated that Vinay "was literally at the top of our list for discussion when our surgeon arrives, and we have reliable word that this will be in the next several days." (Exhibit 7, page GOY 1) Giddins felt that Vinay needed a definitive repair before the end of March. He indicated that if the operation could not be undertaken in Winnipeg then it would be necessary to transfer him out of province.

CONSENT

The Goyals went to the Heart Centre to meet Odim on March 1. Vipan Goyal specifically recalled that his wife asked Odim if he had done this type of procedure before, and was told that he had. Sheena Goyal recalled that Odim said to her that he would not touch a child if he had not done the operation before. Vipan Goyal recalled that he was upset and angry with his wife for asking Odim such a question. He admitted that he had a great respect for doctors and that he was not one to question what they told him.

Sheena Goyal said that she and her husband told Odim on more than one occasion that he was like God to them. Vipan Goyal recalled that Giddins had told him earlier that Odim was coming to Winnipeg from Boston and that he was one of the best. The Goyals also indicated that once the HSC had arranged to have a surgeon in Winnipeg, there was no discussion or suggestion from the VCHC that Vinay be sent out of province.

Odim said he told the Goyals about the risks of being on bypass (bleeding, organ dysfunction, pulmonary problems) and the risk of the procedure (removing the shunts). Odim testified that the longer the bypass time, the higher the probability of problems with these issues, but he said he did not explain that to the Goyals. He only told them that the procedure would take six to eight hours. Odim said he told the Goyals this was a moderate risk case, and that out of a hundred babies, ten might not make it. He also told them about problems with non-fatal complications, and what would happen if Vinay did not have the operation.

There was some discussion as to whether or not the operation should be performed in Winnipeg, and the Goyals asked Odim about his experience. Odim testified that he told them that this was his first position, but that he had trained in centres that had done cases like Vinay's. He also said that he had been intimately involved in both the pre-operative and post-operative care of those types of patients. Odim testified that he did not elaborate to them what he meant by intimately involved. Nor did he actually say that he had been involved in the intra-operative or surgical part of the care of patients like Vinay. When asked of his own experience, he said, "from the operative point of view of issues of doing shunts and doing the procedure, I had experience with a number of cases like Vinay." (Evidence, page 24,318) He testified, however, that he had never placed this type of VSD patch as a primary surgeon. However, he did not provide the Goyals with this information.

The Goyals provided their consent to the procedure. The operation was scheduled for March 17.

Vinay's case was one of some complexity. Odim testified that when the decision was made to perform Vinay's operation in Winnipeg, he did not formally or informally invite other members of the team to raise concerns or to discuss whether or not they felt the team was ready to proceed with this patient. Vinay's case was presented on February 21. However, Giddins and Odim were the only doctors in attendance. In a letter dated March 1, Odim wrote to Giddins, "It is clear the progressive course of cyanosis in this child and his palliated condition require surgical correction. We plan to bring the family and child to clinic for preliminary discussions and evaluations." (Exhibit 7, page GOY 4)

PRE-OPERATIVE CONDITION

Vinay was admitted to the Children's Hospital at 1145 hours on Wednesday, March 16, 1994 for surgical correction of his condition. On examination, Vinay was cyanotic with clubbed fingers. Since March 9 he had been treated with an antibiotic for an upper respiratory tract infection. In Vinay's pre-operative assessment, a physiotherapist heard breath sounds present throughout all lung fields, with a slightly harsh sound, especially in the left upper lobe.

At 1600 hours, Dr. H. Grocott, the anaesthesia resident, examined Vinay's chest and determined that his air entry was clear. He noted the child had had a mild upper respiratory-tract infection a week earlier with a runny nose, but no cough or fever. He assigned Vinay an anaesthetic class of ASA IV and noted that he was fit for anaesthesia. Swartz, the attending anaesthetist, also saw Vinay pre-operatively. She reviewed his history and tried to examine him. Both Grocott and Swartz made entries on the chart that the examination was difficult because Vinay was unco-operative. Swartz listed anticipated problems: arrythmias (irregular heart rhythm), coagulopathy and right ventricular failure post-operatively. She also assessed the child as ASA IV.

A chest X-ray taken on March 16 indicated that Vinay's lungs appeared essentially normal. The heart remained slightly enlarged, with evidence of right ventricular hypertrophy.

THE OPERATION—MARCH 17

On Thursday morning, Vinay underwent a complete repair of a double outlet right ventricle and Tetralogy of Fallot. The operating team is set out in the accompanying chart.

TABLE 6.3: Persons involved in the operation on Vinay Goyal, March 17, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistants	B.J. Hancock, I. Al-Githmi (resident)
Anaesthetists	J. Swartz, H. Grocott (resident)
Scrub nurses	C. Youngson, S. Scott
Circulating nurses	C. Weber, B. Zulak, C. McGilton
Perfusionists	M. Maas, T. Koga

In 1992 Dr. Kim Duncan had indicated in a letter to Collins that his long-term plan for Vinay called for a homograft reconstruction of the pulmonary valve in two to three years. A homograft reconstruction involves using cadaver heart tissue to reconstruct the valve. The approach Odim took was a transannular reconstruction. In this procedure, the annulus or ring of the valve is sliced open to widen it and a pericardium patch (a patch taken from the patient's own heart sac) is sutured over the slice to keep the passageway enlarged.

Over time, Vinay's pulmonary valve had become atretic (or non-functional). Odim therefore also performed a pulmonary valvectomy—this involves removal of the atretic pulmonary valve leaflets. Odim explained that he chose not to perform a valve replacement such as Duncan had planned because Vinay's anatomy and physiology would not tolerate the resulting transannular repairs and the regurgitation that might result. As well, Odim said that putting in a valve in a small child meant that the child would have to undergo repeated operations as he grew.

In addition, Odim placed a Dacron patch over the VSD, cut away the muscle in the right ventricle, closed the patent foramen ovale and removed the Blalock-Taussig shunts that Duncan had placed in Vinay.

No witness to this Inquest suggested that there was anything inappropriate in the diagnosis or in Odim's surgical plan.

TABLE 6.4: Length of phases of the operation on Vinay Goyal, March 17, 1994

Phase of the operation	*Time taken*
Induction	1 hour 13 minutes
Total Bypass	4 hours 19 minutes
Aortic cross-clamp	1 hour 33 minutes
Total surgical time	8 hours 7 minutes
Total operating-room time	10 hours 5 minutes

Fifty-five minutes of partial bypass was required before Vinay was completely weaned from the CPB machine. (Partial bypass is used to support the circulation until the heart functions well enough to allow complete separation from bypass.) It took two attempts and use of inotropic drug support before Vinay could be weaned.

An intra-operative echocardiogram led Giddins to conclude that there was good ventricular performance and an intact VSD patch. However, when transferred to the PICU, Vinay was receiving infusions of three inotropic agents: amrinone, epinephrine and dopamine. The doses of amrinone and epinephrine were moderately large, while the dose of dopamine was relatively low. The use of three inotropes was a sign of the weakened condition of Vinay's heart.

Hudson believed that during the operation there was evidence that the patch had not been successfully applied. One piece of evidence came from the intra-operative measurements of oxygen saturations in various parts of the heart. These measurements showed that the oxygen saturation in the pulmonary artery was ten per cent lower than the level in the right atrium. Such a difference was a sign of a possible leak, leading to shunting. In his report, Hudson wrote:

> The most likely site for shunting would be around the VSD patch, because the patent foramen ovale had been closed with sutures. (Exhibit 307, page 3.4)

Hudson also commented on a murmur heard on March 18 in the PICU that also indicated a residual shunt might be present. This murmur had not been heard the day before and was consistent with there being a leak around the patch.

POST-OPERATIVE COURSE

Overall condition

Vinay remained in the PICU for 31 days until he was taken back for a second operation that was required because of a leak in the patch over the VSD. That leak was not confirmed until two weeks after surgery. During Vinay's time in the ICU, his course was complicated and his condition fragile. He suffered recurring respiratory difficulties and, except for the week from March 23 to 30, he remained intubated and ventilated. A series of chest X-rays taken during his month-long stay in the PICU indicated that at various times Vinay was suffering from pulmonary edema (a fluid buildup into the lungs from the heart), atelectasis (a collapse of lung tissue) and/or pneumonia. Treatment of the pulmonary edema started to compromise his kidney function. He had episodes of heart block with a slow heartbeat, which required treatment with a pacemaker. (Heart block occurs when there is a blockage or interruption of the electrical impulses that regulate the heart beat.) He also had recurring fevers and infections that were treated with antibiotics.

Breathing problems

Shortly after Vinay was transferred to the ICU, the Goyals spoke with Odim. They were told that the two to three days immediately after surgery were the most difficult. After Vinay was extubated, he received oxygen by facemask. By March 25 the lower lobe of his left lung had collapsed and a special pressure mask was placed on his face to assist him with his breathing. Sheena Goyal testified that he looked very uncomfortable under this mask.

> One day he was okay, and the next morning when I went in, he had that pressure mask on his face, and it was giving [him a] really hard time to breathe. So he couldn't sleep for four days and four

> nights when the mask was on his face, and his tongue was out, like he was wanting me to take it out (indicating), but, like I was helpless, I couldn't do anything. I just sat there. (Evidence, page 936)

She asked if the decline in his condition meant that there were problems with the initial operation. According to her testimony, she was assured that all was well. Eventually her son again needed to have mechanical ventilation.

Heart problems

In time Vinay developed biventricular failure, where both ventricles failed to perform their pumping adequately, and required almost continuous inotropic support to sustain his struggling heart. Echocardiograms done on March 21 and March 25 showed a small VSD patch leak. While this leak was possibly tolerable, a March 29 echocardiogram and March 30 cardiac catheterization indicated there was a buckling of the VSD patch. There appeared to be two leaking sites in the VSD patch.

Vinay was suffering from what was termed volume overload—in this case, an excess of blood in his right ventricle. This excess of blood was likely coming from the VSD (which was not fully patched) and through Vinay's pulmonary valve opening. Blood could flow through that valve opening in the incorrect direction because the valve leaflets, which had not been properly formed, had been removed during surgery.

CONCERNS OF THE NURSES AND THE FAMILY

As matters progressed and as Vinay spent more and more time in the PICU without showing signs of improvement, both the nurses and the family became concerned. According to Feser, it was usual for VSD patients to be stable when they entered the PICU and to leave the unit after a two or three-day stay. She became alarmed when this did not occur with Vinay. The family also became more and more concerned as to the care that Vinay was receiving, as well as to whether or not he was improving adequately. At one point, the Goyals called a family friend who was a pediatric cardiologist in Toronto. Their friend called Odim and discussed the case, but there was no indication as to what came of that discussion.

DECISION TO REOPERATE

A heart catheterization showed that Vinay's problems had not been solved and his condition was deteriorating. The problem could be addressed only by either replacing the valve or fixing the leak. Odim chose the latter option. It was made clear to the Goyals that there was no option left but to re-operate on Vinay to correct the leaking patch. The fact that this was a high-risk operation was clear to them. There was no discussion about trying to transfer Vinay to another heart centre. Indeed, the evidence tends to suggest that he was in no condition to be transferred any great distance.

Nonetheless, one would have thought that the option would have been raised with the family. Furthermore, by the time the Goyals were being asked to provide consent to a second operation, which did not take place until April 18, a second child, Jessica Ulimaumi, had died following pediatric cardiac surgery at the HSC.

THE CASE OF JESSICA ULIMAUMI

ISSUES

Jessica Ulimaumi died on March 27, 1994, after undergoing pediatric cardiac surgery on March 24. Her case gives rise to the following issues:

- Was there an inappropriate delay between the time of her diagnosis and the date of the operation on her heart?
- Was Jessica's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Jessica healthy enough to undergo an operation?
- Did the length of surgery contribute to her death?
- Were the repairs properly carried out?
- Did irregularities in the process of weaning her from ECMO contribute to her death?
- What was the cause of death and was it preventable?
- Should this death have triggered a review of the program?

BACKGROUND AND DIAGNOSIS

Jessica Ulimaumi was an Inuk child born on August 18, 1993, at the Arviat Nursing Station in the Northwest Territories. Jessica had a normal delivery at full term, with no apparent complications. Assessment at birth gave no indication of any heart problems. At the request of her mother, Jessica was adopted by relatives, Emalee and John Ulimaumi.

During a September 3, 1993, medical checkup at the Arviat Nursing Station, an examining nurse heard a loud heart murmur in Jessica's chest. This was confirmed by the visiting general practitioner, Dr. Banach, who referred Jessica to Dr. D. Grewar, in the Department of Pediatrics at St. Boniface Hospital. Tests conducted there revealed enlargement of the heart, increased pulmonary blood flow, and a 10 millimetre (in diameter) ventricular septal defect.

Grewar referred Jessica to the Variety Children's Heart Centre. Accompanied by her mother and an interpreter, she was seen by Giddins on October 1. Jessica's length (54 centimetres) and weight (3.7 kilograms) were low for her age, placing her at the twenty-fifth percentile. Giddins found evidence of mild respiratory distress. Jessica was breathing rapidly at 55 breaths per minute. Her lungs appeared to be overinflated, and she had intercostal in-drawing. These were all signs of breathing difficulties. A heart murmur was heard. Giddins was able to palpate (or feel with his hand) Jessica's liver at a distance of three centimetres below the right costal margin. This was a sign of possible congestive heart failure. However, Jessica's colour and the circulation in her limbs were good.

She was diagnosed as having:

- a five-millimetre-diameter atrial septal defect with a left to right shunt

- mild tricuspid valve regurgitation
- enlargement of the left and right atria, as well as the right ventricle
- prominent right ventricular muscle bundles (which were non-obstructive)
- a nonrestrictive 7–8 millimetre ventricular septal defect with outflow extension and left to right shunting.

The fact that the VSD was nonrestrictive meant that the pressures in Jessica's left and right ventricles were equal, putting Jessica at risk of developing pulmonary hypertension.

In a letter to Grewar dated October 14, Giddins said, "In summary, Jessica is a six week-old infant with a heart which is currently required to work additionally hard due to left to right shunting present at both the atrial and ventricular levels." (Exhibit 13, page ULI 4) He also said he started Jessica on furosemide (Lasix), a diuretic, because she had mild respiratory distress and lived a long way from a hospital. He planned to see her again in early December or sooner, if symptoms of congestive heart failure developed.

In the letter, Giddins gave no indication that Jessica needed surgery. Nor was there any mention of getting Jessica stronger in preparation for possible future surgery. In fact, no specific medical plan was recommended, other than giving her a diuretic and reassessing her in December.

In his evidence as to why he concluded that Jessica did not need surgery at that time, Giddins pointed out, as he had in the Caribou case, that small ASDs and VSDs in young children often closed on their own without surgical intervention. Jessica was also not in congestive heart failure—a state where the heart is failing to meet the needs of the body—and so performing a surgical procedure on her at that time held more risk than doing nothing. It should be noted that evidence presented to this Inquest suggests that Jessica's defect was large, rather than small. Despite this, Cornel, in his testimony said that it was his practice not to operate on patients with a similar problem until it was making them ill. He said that this rarely occurred before six weeks of age and often not until the child was more than seven months old.

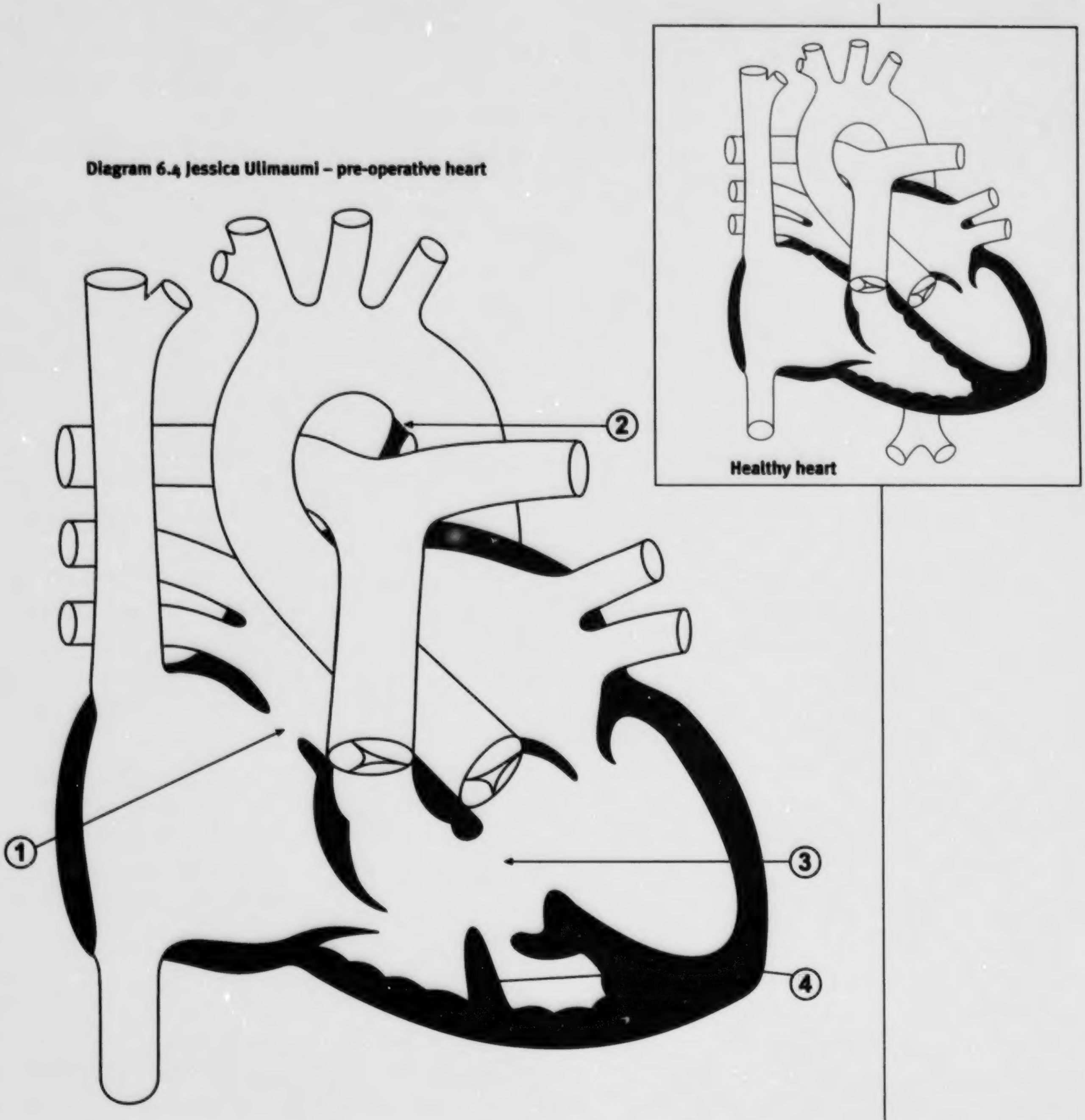
Giddins believed that, given the condition of Jessica's heart, it was essential that her condition be continuously monitored, since congestive heart failure could appear quickly and could be a prelude to death. For that reason, he sent a copy of the letter to Banach and the Arviat Nursing Station. However, Giddins did not specify what additional problems might arise. Jessica returned to Arviat.

In early November, Jessica was again taken to the Arviat Nursing Station. The nurses diagnosed her as having a rapid heart rate and respiratory distress. They arranged to have her seen by Grewar at the St. Boniface Hospital. He in turn referred her to Giddins, who saw her on November 15.

Giddins noticed she had been receiving a lower dose of furosemide than previously ordered and increased it to the amount that he had prescribed. On examination he found that Jessica had gained a pound in weight since her October visit. Her breathing was rapid at 65 breaths per minute, with mild to moderate in-drawing. Her liver span was normal, different from the first examination where it extended below the costal margin. The echocardiogram revealed that the previously noted right ventricular outflow tract musculature (the muscle bundles) was becoming obstructive, causing her heart to work even harder.

In a November 18 letter to Grewar, Giddins wrote, "Jessica continues to demonstrate findings of a considerable left to right shunt at ventricular septal defect level, but it would appear that her lungs are being protected somewhat from high pressures by the right ventricular outflow tract musculature. While she is relatively tachycardic [has a rapid heart beat] and tachypneic [is breathing rapidly], I do not believe she is sig-

Diagram 6.4 Jessica Ulimaumi – pre-operative heart



1 – Atrial septal defect
2 – Ligamentum arteriosus (former ductus arteriosus)
3 – Ventricular septal defect
4 – Abnormal right ventricular muscle bundles

nificantly compromised at this time." (Exhibit 13, page ULI 15) He recommended an increase in her formula concentration and a liquid iron preparation to assist her growth. He indicated that with improved growth, her symptoms might diminish. He also encouraged the nurses at the Arviat Nursing Station to contact him with any concerns and suggested a reassessment appointment in February 1994.

When Jessica returned to Winnipeg in February, tests revealed that the VSD was not closing and that her problems were becoming more serious. She had a minimally restrictive, moderate to large VSD, with a large associated left to right shunt, a restrictive atrial septal defect and biventricular hypertrophy with reduced ventricular compliance (Exhibit 13, page ULI 78). (Her enlarged ventricles were not able to cope with the flow of blood as well as they ought to have.) However, on the Day Care Abstract for her heart catheterization, Giddins also wrote, "No significant ventricular outflow obstruction." (Exhibit 13, page ULI 21) After seeing the results of the tests Giddins referred Jessica to Odim. By this point, Jessica had also been diagnosed with failure to thrive.

THE DECISION TO OPERATE

On March 1, Odim reviewed the heart catheterization report. In a letter to Giddins, Odim described Jessica as having a minimally restrictive ventricular septal defect, with elevated-end diastolic ventricular pressures (one of the earliest signs of the heart's failing as a pump), and with no evidence of significant ventricular outflow tract obstruction. He wrote, "This ventricular septal defect clearly will not close on its own." (Exhibit 13, page ULI 9)

In a separate letter to Giddins, Odim described meeting Jessica and Emalee Ulimaumi with an interpreter on March 1. He wrote, "I explained to the mother, via the interpreter, the importance of surgical repair of this ventricular septal defect. The mother appeared to understand the necessity for this intervention as well as the risks. We should plan to bring Jessica back within the next four to six weeks in order to repair this lesion. Hopefully by then she might have gained some additional weight." (Exhibit 13, page ULI 10)

On March 18, Jessica was admitted to the Churchill Health Centre with nausea, vomiting, fever and diarrhea. A chest X-ray showed no signs of congestive heart failure. She was diagnosed as having gastroenteritis and continued to have diarrhea after discharge. Dr. Smith, in Churchill, spoke with Giddins about Jessica's condition and arrangements were made for Jessica to be admitted to HSC on March 23 in preparation for surgery.

PRE-OPERATIVE CONDITION

Jessica was admitted to the HSC on Wednesday, March 23. The cardiology note written by Dr. Salvador described Jessica as being well hydrated with no congestive heart failure. However, she had lost 500 grams since her last examination at VCHC. He wrote, "She definitely looks wasted. Fit for the OR – need to observe for stools here." (Exhibit 13, page ULI 54)

The pre-operative physiotherapy assessment indicated that Jessica had good air entry, with a clear chest. No pre-operative concerns were identified. Reimer, the anaesthetist, reviewed the chart and examined Jessica. He wrote, "Increased risk due to age, weight, CHF. Proceed as planned." (Exhibit 13, page ULI 67)

A chest X-ray done that day showed an enlarged heart with a prominent increase in pulmonary blood flow (as compared with February 16). There were new added densities suggesting atelectasis and possibly some edema in the lung tissue. This was a sign of potential chest problems that could become more severe following surgery.

CONSENT

There are signed forms on the medical chart indicating that Emalee Ulimaumi gave her written consent to the admission of her daughter to the HSC and to her operation on the morning of March 24, 1994. There is also information on the file that an Inuk interpreter assisted Emalee Ulimaumi in understanding what was going on.

The Ulimaumi family did not participate in the Inquest proceedings. Therefore there is no information available from their perspective as to what they were told before signing the consent forms on the medical chart.

THE OPERATION—MARCH 24

The operation took place on Thursday, March 24. Jessica was to undergo a complete repair of the ventricular septal defect with a Dacron patch, suture closure of the atrial septal defect and ligation of the ligamentum arteriosus. The operating team is set out in the accompanying chart.

TABLE 6.5: Persons involved in the operation on Jessica Ulimaumi, March 24, 1994

OR team member	*Persons involved*
Surgeon	**J. Odim**
Surgical assistants	**B.J. Hancock, I. Al-Githmi (resident)**
Anaesthetists	**H. Reimer, H. Grocott (resident)**
Scrub nurses	**C. Youngson, S. Scott**
Circulating nurses	**B. Zulak, S. Scott, C. Weber**
Perfusionists	**M. Maas, D. Smith**

TABLE 6.6: Length of phases of the operation on Jessica Ulimaumi, March 24, 1994

Phase of the operation	*Time taken*
Induction	**1 hour 12 minutes**
Total bypass	**8 hours 43 minutes**
Aortic cross-clamp	**2 hours 7 minutes**
Total surgical time	**13 hours 33 minutes**
Total operating-room time	**15 hours 5 minutes**

Jessica was weaned from bypass at 1313 hours, after the initial repair. However, the operation was marked by the fact that this initial attempt to repair the VSD was unsuccessful, with evidence of a leak in the VSD patch first shown by the values for oxygen saturation in different parts of the heart. An intra-operative echocardiogram, performed at 1530 hours, demonstrated that there was a residual nonrestrictive left-to-right shunt under the right aortic valve cusp. This confirmed the suspicions that the patch closure of the VSD was incomplete. Odim had to attempt the repair a second time. The second attempt required an additional period of bypass of two hours and twenty-four minutes and an additional aortic cross-clamp time of forty-four minutes.

The total surgical time from beginning the incision to closure of the incision was thirteen hours and thirty-three minutes. Jessica was on bypass a total of six times, with a total CPB time of eight hours and forty-three minutes. She underwent aortic cross-clamping twice, for a total of two hours and seven minutes. The lengthy times were necessitated by the decision to redo the repair. In his report, Soder described the total bypass and cross-clamp times as very prolonged.

In his post-operative note Odim wrote that Jessica had a large VSD and that after the first repair, a large leak was still present. As a result, Jessica required a second period of CPB and aortic cross-clamping.

However, according to Youngson, Odim indicated that one of the problems with the repair was the type of suture that had been provided to him.

> One of the comments that Dr. Odim made to me at that point in time was that if he had the right kind of suture material, this would never have happened. And I remember being very upset about that and disturbed by that comment, because I felt that he was blaming me for the fact that we had to go back and redo this repair. (Evidence, page 8,379)

There was no mention of the problems with sutures in the operative note. Also, whether Odim was correct or not in his assessment of the cause of the problem with the repair, it would appear that the time and place to have arranged for appropriate sutures was in February, when Youngson had sought his input.

Following the completion of the second corrective procedure, several unsuccessful attempts were made to wean Jessica from the bypass machine. During each attempt to wean her from the machine, Jessica's heart did not give an adequate response.

Jessica had very high pulmonary pressures that did not respond to the drugs that were administered. In addition, the anaesthetist had problems maintaining adequate ventilation of Jessica's lungs. During investigation of the problem, the endotracheal tube was dislodged from her throat. While reinserting the tube, Reimer had difficulty passing the tube below the vocal cords (Exhibit 13, page ULI 82).

A second intra-operative echocardiogram was done at 2015 hours. This showed no apparent ventricular outflow obstruction, a possible minor residual VSD shunt, a distended atria (with the right side more distended than the left) and mild to moderate tricuspid regurgitation. The lack of any obstruction focused attention on the other problems revealed by the echocardiogram. The possible VSD shunt indicated that the repair might still be incomplete. The distended atria indicated that the ventricles were struggling to pump blood. Hudson said: "The atrial distension indicates biventricular failure, right worse than left." (Exhibit 307, page 2.5) This meant that the ventricles were not capable of performing their proper function. This condition may have resulted from myocardial stunning, itself the result of the prolonged CPB and cross-clamp times.

The decision was made to transfer Jessica to the PICU and then to place her on another form of cardiopulmonary bypass, called an extra-corporeal membrane oxygenation (ECMO) machine. ECMO is a form of long-term cardiopulmonary bypass, which assists the heart in pumping and oxygenating blood. It is used in situations where a patient's heart cannot beat on its own but might recover sufficiently within a short time (up to a few days in length).

At the end of the surgical procedure, the nurses could not account for one suture needle. (This missing needle is of particular significance, since the autopsy report indicated that a needle was found near the cannulation site.) Losing a needle during the course of an operation is, surprisingly, a rather common event. During a cardiac operation, several hundred needles may be used. Cornel testified that it is not unusual for a needle to be dropped on the floor, to be lost in the drapes covering the patient, or even to get caught up in the surgeon's operating gown.

That is not to say that loss of a needle is a routine matter, for there is always cause for concern when this happens. However, the evidence established that needles are often misplaced during a lengthy operation. When a needle is lost and there is reason to suspect that it may have been inadvertently left or dropped inside a patient, a portable X-ray machine may be brought into the operating room to determine if the needle is indeed in the patient. An assessment is done to determine if it is necessary to retrieve the needle immediately or to leave it until the patient's condition has improved. As long as the surgeon is satisfied that the loss of the needle does not place the patient in jeopardy, matters will proceed normally.

In the OR, the nursing staff discovered that the needle was missing when they performed their needle count. At 2106 hours on the day of the operation, Celine Weber, the scrub nurse, filled out a general incident report form reporting a missing needle. She recorded, "Long case 0730 to 2200 hours many needles used (over 170). Surgeon notified, no X-ray done as is low priority at this time." The form was signed by Odim (Exhibit 19, Document 277B).

Odim's recollection was that, given Jessica's heavily compromised condition and the fact that there seemed to be no reason to believe that the needle was left inside her, he felt it was appropriate to send her to the PICU.

How Odim could have known that the needle was not left inside his patient is hard to determine. The evidence shows that the nurses had no idea where the needle was. If it had been inside the patient, an X-ray would probably have disclosed its location. However, while Odim should have ordered a chest X-ray in the operating room, his failure to do so does not seem to have had an impact on Jessica. There is some evidence to suggest that the needle was not left inside Jessica. Several post-operative chest X-rays were taken of her chest area in the PICU. None of them showed the presence of a needle near her heart before her death.

Thus, the OR nurses followed the proper procedure in completing an incident report about the fact that, at the end of the operation, they were unable to locate one needle. What happened to the needle that was lost during the operative procedure has never been resolved satisfactorily. The fact that the lost needle was recorded and reported to Odim was appropriate, and procedures in this regard were followed properly. The likely origin of the needle that was discovered by the autopsy will be dealt with in the discussion of the events surrounding Jessica's death.

POST-OPERATIVE COURSE

Jessica was admitted to the PICU at 2255 hours, accompanied by two anaesthetists, two perfusionists, an OR nurse and Odim. She was extremely pale and her extremities were cool. She had severe fluid retention—her body had retained an additional 1,280 millilitres of fluid while on bypass. The admitting nurse, Colleen Kiesman, recorded that Jessica's face was so swollen (another sign of fluid retention) that she could not open Jessica's eyes to check her pupils.

Jessica continued to experience bleeding problems throughout her stay in the PICU. Her urine had blood in it, and there was continuous bloody oozing from her sternum, which was a sign of a coagulopathy or clotting disorder. Coagulopathy problems can arise when a patient has been on bypass for a long time. Blood cells react differently when pushed through a bypass machine, as opposed to when they are normally pumped by the heart through the lungs. Thus, a lengthy bypass can damage the patient's blood cells and limit their ability to clot. For this reason, a wound that would normally clot quickly can turn into a serious site of bleeding following a prolonged period on bypass. Because ECMO is a type of bypass machine, it can also interfere with blood clotting.

On Friday, Jessica was still on ECMO, which was being operated by a perfusionist. She had continued to bleed from her chest into special drainage tubes. (Chest tubes are inserted post-operatively to drain fluid or air from around the lungs, thus allowing the lungs to expand.) While the blood drained through the chest tubes, the tubes were not the cause of the bleeding. That day, Jessica lost 525 millilitres of blood in six hours. To compensate for this loss, she was given blood transfusions. A chest X-ray showed that her edema and atelectasis were improving, but an echocardiogram showed that her heart was deteriorating. Jessica had increased left atrial and ventricular enlargement, decreased septal motion and a residual VSD shunt.

In an attempt to find a source of bleeding, Odim re-explored Jessica's chest in the PICU on Saturday at 2325 hours. He reported that she had a generalized coagulopathy, some leaking of blood from around the aortic cannula site (to which he added a second suture), and some blood within the mediastinum (the space around the top of the heart in the chest). The blood loss from the chest tubes continued to be enormous. Jessica lost a total of 2,732 millilitres in 24 hours. Numerous transfusions of blood and blood products were given.

On Sunday, March 27 there was still significant oozing of blood where the lines entered Jessica's body. The sternotomy site also continued to ooze, and the chest tube losses totalled 1,220 millilitres of blood over six hours. This means that over a 30-hour period, she lost eight times her blood volume. Odim was concerned about the lack of improvement in her ongoing coagulopathy. He considered it unlikely that her condition would improve while she remained on ECMO. Indeed, the longer she remained on the machine, the worse were her chances of recovery.

Odim decided to wean her from ECMO in the PICU, a decision that Kesselman agreed with, since Jessica was in too fragile a state to be moved to the OR. The decision to perform the procedure in the PICU was risky. In his testimony, Kesselman said that it had been never successfully done in the unit. In her testimony, Feser said that the PICU nursing staff were not familiar with weaning from ECMO or decannulating lines, one of the steps of the weaning process. "It is not something that you do on a basis of, you know, very short notice." (Evidence, page 29,947) The cardiac bins that the PICU staff had asked Odim to help them prepare were still not ready, as Odim had not yet responded to the request for a list of equipment.

Kesselman said that there was no discussion of requesting OR nursing assistance. Hancock scrubbed in to act as Odim's assistant, while Kesselman and other PICU nurses were to perform essential monitoring functions. A perfusionist, Dave Smith, was present and continuing to provide perfusion services for the ECMO. There was no anaesthetist present, although an anaesthetist's presence is required by policy for all surgical procedures at the HSC. Weaning from ECMO would appear to be a surgical procedure. An anaesthetist would have been able to provide assistance with ventilation, monitoring and relieving pain, providing other medications and treating blood problems.

Weaning Jessica from the ECMO machine should have been done in a more organized fashion, with a properly prepared surgical team. Odim seems to have failed to appreciate that fact. He proceeded without ensuring that there was appropriate staff in place to assist in the procedure. He did not direct that appropriately trained nurses be called in, although the evidence established that this assistance was available if requested.

The evidence suggested that once the procedure to remove Jessica from the ECMO machine started, matters quickly grew chaotic and critical. Jessica had been losing considerable amounts of blood before the procedure, and her condition was already badly compromised by her steady deterioration after the operation.

On removal of the inferior vena cava cannula, Jessica experienced a sudden and massive loss of blood. According to Odim and Hancock, the blood loss occurred through the opening at the cannula site. Odim could not staunch the flow of blood quickly or adequately. At Jessica's bedside there were no Satinsky clamps (the type of clamp that is best suited for clamping such openings in a blood vessel). One of the ICU staff was sent to the OR supply room to get one. This took minutes to accomplish, during which time Odim attempted to decrease the loss of blood by pressing his fingers against the cannula opening.

Once the clamp arrived, Odim attempted to suture the site closed, but with the already-heavy loss of blood, his efforts proved futile. Jessica died before he could close the site completely. Had Odim responded earlier to Feser's request for a list of equipment he needed in the PICU, the proper clamps would likely have been in place. The request for the clamps might also have alerted the PICU staff to the fact that Odim intended to undertake such procedures in the PICU.

Jessica was a small child. The available evidence established that the total amount of blood in her system would have been about 500 millilitres (half a litre). It would not have taken very long for her body to drain itself of all of its blood through a sustained opening such as a cannula site, in the absence of adequate pressure on the site.

However, what went unnoticed during the procedure was the fact that either the surgeon or his assistant had failed to clamp the inferior vena cava cannula line after removing it from Jessica. It is quite possible that Jessica bled to death through this unclamped line.

In the normal procedure for weaning a patient from bypass or ECMO, the surgeon announces that he or she is going to remove a venous cannula. At this point, the perfusionist will clamp the venous cannula line at the pump. The surgeon is expected to clamp the line at the patient's end.

Odim did not clamp the line. This was an error for a number of reasons. Air can enter the unclamped line and, ultimately, the machine and then the patient, if it is necessary to go back on bypass. Blood that is in the

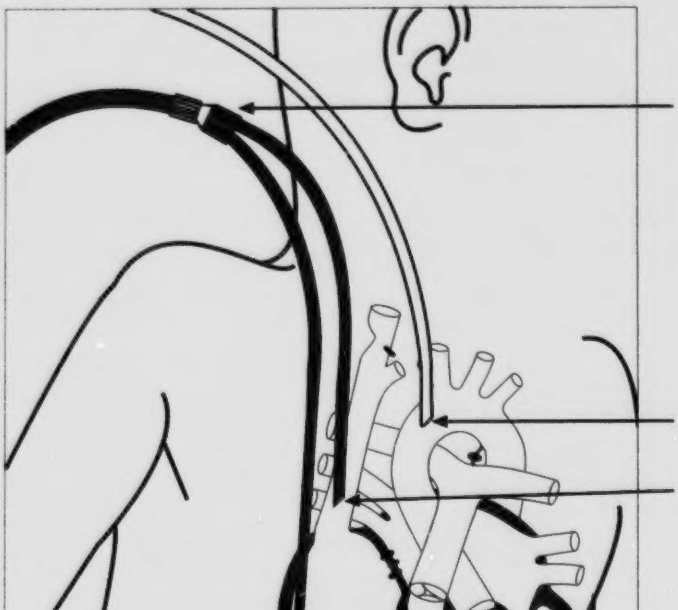

y-connector joining the venous cannulas
arterial cannula in aorta
venous cannula in superior vena cava
venous cannula in inferior vena cava

Diagram 6.5 Depiction of the connection of the ECMO lines to Jessica Ulimaumi.

line can be lost since it will simply drain out of the line. Finally, there is the danger that the patient can bleed to death. This danger arises from the fact that the lines from the inferior vena cava and the superior vena cava are joined together by what is termed a Y connector. From this connector, blood flows through a single line to the ECMO machine. If, as happened in this case, the line from the inferior vena cava is decannulated, while the line to the superior vena cava remains cannulated, blood can continue to flow from the child into the line from the superior vena cava. However, that blood can no longer flow into the ECMO machine if, as happened (quite appropriately) in this case, the line has been clamped at the ECMO end of the line. Instead, the blood can simply drain out of the unclamped line that had been connected to the inferior vena cava.

Perfusionist Dave Smith testified that once he heard a member of the team announce that the cannula had been removed, he noted a dramatic increase in the volume of blood he needed to transfuse into Jessica to maintain her pressure. He started to run out of blood to transfuse. "This was happening very quickly, the nurses were bringing blood from the blood bank, albumin. I was adding clear fluid just to keep going, keep the pressure up." (Evidence, page 9,803) According to Smith, someone gave the order to go back on ECMO. Smith said he responded that he had no blood left. "And after that, at that point, they decided to quit I believe." (Evidence, page 9,804)

Jessica went into cardiac arrest during this period. She could not be resuscitated and was pronounced dead at 1216 hours on March 27, 1994. While Odim went to speak to the family, Smith went to look at the child's body.

> At that point, I noticed a venous cannula lying on the bed, beside the baby's chest. It was unclamped. I found that unusual, so I asked—Dr. Hancock was still there. She was across Jessica from Jonah and Murray Kesselman was at the head of the bed. I asked if this had ever been clamped, was this clamped at one time? And they said they didn't think so. They couldn't recall it being clamped. And they wanted to know why, so I proceeded to explain the physics of the situation. (Evidence, page 9,805)

Smith said that next to the cannula there was a flannel sheet that was soaked with blood.

In her testimony, Hancock stated that Odim took the cannula out and handed it to her. At that time Jessica started to bleed seriously.

> I remember thinking, you know, that it wasn't clamped. But at the same time, the big problem was inside where she was bleeding from the inferior vena cava, and it was really just welling right up. (Evidence, page 20,648)

For this reason she said that she and Odim both turned their attention to the bleeding they could see. It was during this period that a nurse was sent for the Satinsky clamp. Odim testified that it was Hancock, not himself, who removed the cannula, under his instruction. He also testified that he was in the process of closing the bleeding site without a clamp. Odim testified that he heard the sound of the siphoning of blood from the heart and noted the decline in the heart's power. At that point he said he recognized that there could not be a clamp on the line. He concluded the major blood loss was from the cannula. Odim stated that the line was then clamped. He testified:

> I don't recall who placed the clamp, whether Dr. Hancock placed it or myself. I just said, listen, we have to get a clamp on the line, and a clamp was got, and the line was clamped, the SVC cannula was clamped. I don't recall whether I did it or B.J. did it. We were sort of looking for a Kelly clamp and the clamp got applied. (Evidence, pages 24,205–24,306)

From Smith's testimony, it appears that Hancock might not have understood the dangers of not clamping the line. An experienced OR nurse might have noticed if the line was unclamped. However, the ICU nurses were not used to, or trained in, operating-room procedures, especially the procedures related to removal of a patient from bypass.

Smith did not complete an incident report about the event. In his testimony he indicated that he believed incident reports to be essentially a nursing responsibility. Smith was, however, quite upset by these events and reported them to Maas, his supervisor. Maas spoke with Odim the following day. He told Odim of the dangers in not clamping the line and the need to conduct these procedures in a manner that allowed the perfusionist a clear view of the lines. In his testimony, Maas said of Odim:

> He acknowledged that a mistake had been made. He was quite straightforward and up front about it and that it wouldn't happen in the future and things would be done in orderly fashion. (Evidence, page 6,932)

Maas said that he did not fill out an incident report on the matter because:

> We are not that familiar with incident reports, I will be quite honest. We don't fill them out because there are no incidents with us that we have ever experienced up to this point. Obviously this is an incident, and we felt the best route to go was a direct route. (Evidence, page 6,932)

It should be noted that the filing of incident reports did not preclude also speaking with Odim.

Odim's account of post-operative discussions differs considerably from the evidence provided by Smith and Maas.

> I ventilated a little bit at the bedside when I recognized at the end that things weren't done as smoothly as things could have been done. Those were sort of my discussions with my team members at the bedside. I don't recall a later discussion with Mike. It's certainly possible that I might have had some words with him.
>
> *Q.* Do I infer from your use of the word "ventilate" that you were angry with them?
>
> *Odim:* At the whole, as I said I think there was a little bit of a break down, and I—nobody was sort of looking at the monitor, and we didn't know when the blood pressure was dropping from the monitor. We were all there. I said well, I am sitting tying a knot and trying to control bleeding, somebody needs to tell us, yell out what's going on, and that didn't happen very efficiently. I was a little concerned that there was a delay to put the clamp on and asked my assistant, when you take the cannula out, don't you always clamp it, and why wasn't that done? And I also, I asked Mr. Smith, that, you know, if the blood pressure goes down, you need to let us know so we go right back on ECMO. So, that was sort of the discussion I had with my team members as, you know, the person in charge to facilitate so that this would not happen again. (Evidence, pages 24,208–24,209)

In later testimony, Odim was presented with Maas's testimony to the effect that he had spoken to Odim about the incident and that in a straightforward manner Odim had acknowledged that a mistake had taken place. Odim said: "Unfortunately I don't recall the specifics of that conversation." (Evidence, page 24,243)

In his patient progress notes, Odim wrote that he had successfully weaned Jessica from ECMO with stable cardiac functions, although inotropic drugs were being administered, for approximately forty minutes. He wrote that she then developed severe bleeding following removal of the inferior vena cava cannula. Odim said that she was placed back on ECMO but could not be stabilized. This report does not capture the confused nature of events. This statement was also contradicted by Dave Smith, who said that Jessica was never successfully re-established on ECMO.

None of the medical staff made an entry in this child's chart indicating that a clamp had not been placed on the IVC venous cannula line, despite the clear importance that this would have had in determining the cause of the baby's death. This omission is a glaring one and bears comment. As noted in Chapter Three the chart or medical record is a crucial source of information. Failure to chart pertinent events would, for example, prevent the Chief Medical Examiner's office from reaching an appropriate conclusion as to whether or not an inquest should be held into a child's death.

Additionally, the medical record is a primary source of information for the family of a deceased child. The HSC as a matter of policy in these cases made the charts available to the families of the children who died in 1994. In this case, anyone reading the Ulimaumi chart would not have been able to determine what occurred in the PICU during the attempt to wean Jessica from the bypass machine, since not all of the material facts were disclosed in the chart. When asked why the clamp issue was not mentioned, Odim said:

> I think the operative report states what happened in terms of the destabilization of the patient during decannulation. (Evidence, page 24,215)

On that point Odim was not correct. The operative report gives little indication of the events disclosed by the evidence.

AUTOPSY FINDINGS

A staff pathologist at the HSC, Dr. Joseph de Nanassy, performed the autopsy. He concluded that the immediate cause of death was "Cardiac arrest post cardiac surgery due to or as a consequence of coagulopathy and hemorrhage during weaning from ECMO." (Exhibit 13, page ULI 22) He noted that her superior vena cava had been narrowed by a suture. This likely was caused during the original surgery. There was also the presence of a needle near the cannula site.

Odim commented on the needle found in Jessica during the autopsy. He felt that this needle was in all likelihood one that was used during attempts at removing Jessica from the ECMO machine in the PICU. In his testimony, Odim said the needle was the needle "from my reinforcement, attempt to reinforce that suture line before I started to massage the heart and aborted that when the blood pressure and the cardiac action was going down." (Evidence, page 24,211) The evidence suggests that the needle likely became lodged in Jessica during the attempt to wean her from ECMO in the PICU and played no role in her death.

The only item in de Nanassy's report that has come under question is his conclusion that Odim's second repair was intact. Two of the consulting witnesses who prepared reports for this Inquest disagreed with this finding. Drs. Walter Duncan and Glenn Taylor[4] both reviewed the autopsy report, as well as the heart specimen. Duncan also reviewed a videotape of the heart echocardiogram done immediately after the second attempt at repairing the VSD. They both concluded that the VSD had not been successfully repaired at all. In other words, both the first and second attempts were not done properly.

Duncan and Taylor concluded that, rather than placing the patch across the hole in the septal wall, Odim had in fact sutured the patch to a muscle bundle that was attached to another part of the wall of the ventricle. As a result, blood continued to shunt through the opening in the septal wall in the VSD and heart performance remained poor.

Neither doctor could point to this factor as a cause of death, since the events that led directly to Jessica's death related to the failed attempt at removal from the ECMO machine. Both were of the opinion, however, that the failed repair would explain why Jessica did not recover well enough after the operation to be weaned from the CPB machine in the operating room or be weaned from ECMO. Indeed, if the repair had not been properly done, it would have been impossible to wean Jessica from ECMO.

Duncan conceded that the heart specimen he reviewed was not in very good condition. As a result, it might not have reflected the true condition of the repair. However, he also reviewed the echocardiogram videotapes (something that he specializes in doing as a pediatric cardiologist) and concluded that the tapes confirmed his view that the repair was unsuccessful.

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[4] Dr. Glenn Paul Taylor received his medical degree from the University of British Columbia in June 1976. He completed post-graduate training at Toronto General Hospital in 1976, as well as the University of British Columbia in 1977 and the University of Toronto in 1979. He was appointed a fellow of the Royal College of Physicians in Canada in anatomical pathology in December 1981. He was certified in anatomic pathology by the American Board of Pathology in June 1991 and awarded special qualifications in pediatric pathology in June 1992 by the same body.

A member of the hospital staff at the Toronto Hospital for Sick Children, he was also affiliated with the University of Toronto Department of Laboratory Medicine and Pathobiology, the University of Toronto Department of Pathology and the University of British Columbia Department of Pathology.

At the time of his evidence, Taylor was a staff pathologist with the Department of Pediatric Laboratory Medicine at the Hospital for Sick Children in Toronto as well as an associate professor in pathobiology, Department of Laboratory Medicine, at the same institution. He was also a consultant pathologist at the British Columbia Children's Hospital.

Taylor has delivered several lectures, workshops and courses on pathology and has published extensively in the area. He was acknowledged as having special expertise in anatomic pathology and was permitted to give expert evidence to the Pediatric Cardiac Surgery Inquest in that area.

Duncan concluded that, because of the failed operation, the cannula site would have been exposed to very high blood pressures while Jessica was on ECMO. This would explain why there was so much damage to Jessica's cannulation site when the venous cannula was first removed. The increased pressure at this location would have resulted from the fact that the blood was not flowing properly, as a result of the failed repair. Duncan therefore concluded that the failed repair had a direct bearing on what occurred in the PICU during the ECMO weaning process.

De Nanassy thought that Taylor and Duncan had reached their conclusions from assessments made on the study of a dissected heart specimen. He stood by his initial report, which was based on examination of the heart shortly after death. However, Duncan's evidence, based on his viewing of the echocardiogram tapes, is persuasive. This evidence clearly suggests that the VSD was not properly repaired at the time of Jessica's initial operation.

POST-MORTEM EVENTS

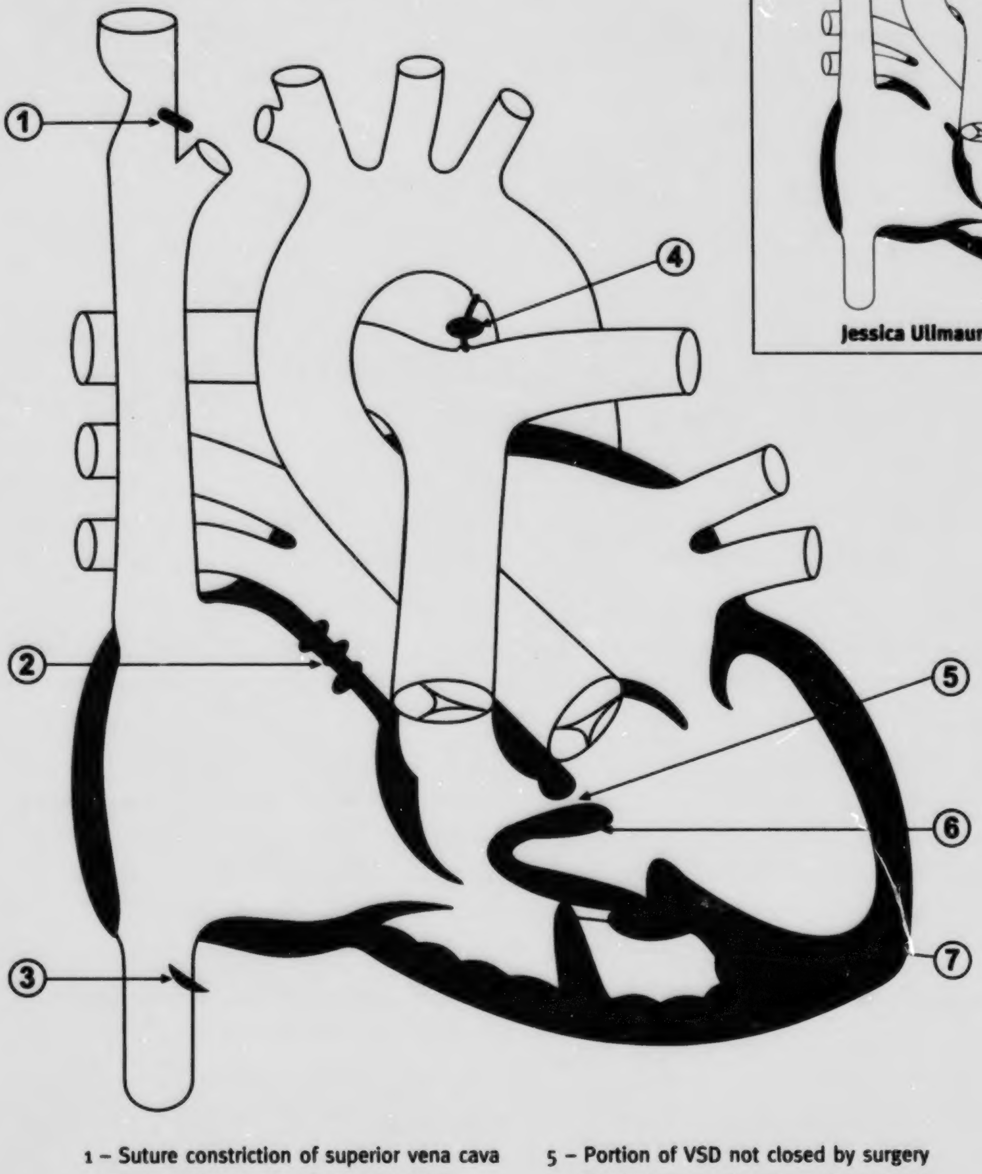
During the course of proceedings it was revealed that the HSC Department of Pathology had retained Jessica's heart following the autopsy. It is not known if this fact was ever revealed to the family. There is no explicit written consent allowing the HSC to retain the heart. While this question did not become an issue during the course of the Inquest, it has been a focus of public concern in other jurisdictions.

The authorization that parents sign when giving consent to an autopsy is an unrestricted authorization. However, parents can, if they choose, place restrictions on the autopsy, and in at least one case, the parents of a child whose death is under examination by this Inquest did so. Despite this, there is nothing in the consent form that provides parents with the knowledge that their child's heart may—and, indeed, probably will—be retained by the hospital.

Some cultures place an emphasis on dealing with the entire body when a person dies. Such cultures may require that limbs that are amputated, organs that are removed, the after-birth, and even hair cuttings must be treated with the same respect as one's body is after death. Even in cultures that do not have such traditions, parents may experience significant stress and anger on discovering that their child's heart was not buried with the rest of their child's body, but was retained in the facility where their child died.

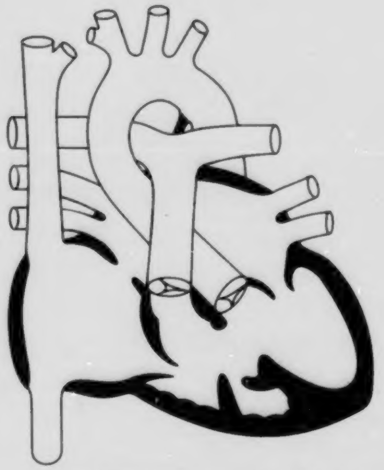
It is recognized that the HSC did not retain the hearts of children who underwent autopsies for capricious reasons. These hearts were used in teaching and were in fact examined as a part of this Inquest. However, the rights of the parents to make an informed decision about what is to become of their child's body cannot be ignored. That gives rise to a recommendation at the end of this report.

Diagram 6.6 Jessica Ulimaumi – post-operative heart



1 – Suture constriction of superior vena cava
2 – Suture closure of atrial septal defect
3 – Surgical needle, inferior vena cava
4 – Ligation of ligamentum arteriosus (former ductus arteriosus)

5 – Portion of VSD not closed by surgery
6 – Patch closure of portion of ventricular septal defect
7 – Patch sutured to right ventricle muscle bundle as opposed to septal wall



Jessica Ulimaumi – pre-operative heart

FINDINGS

As noted above, this case gave rise to the following questions:

- Was there an inappropriate delay between the time of Jessica Ulimaumi's diagnosis and the date of the operation on her heart?
- Was Jessica's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Jessica healthy enough to undergo an operation?
- Did the length of surgery contribute to her death?
- Were the repairs properly carried out?
- Did irregularities in the process of weaning her from ECMO contribute to her death?
- What was the cause of death and was it preventable?
- Should this death have triggered a review of the program?

This case brought to the fore many of the issues that are central to this Inquest. They include questions of inexperience and competence, lack of preparation, failure in team building and communication, and a failure to undertake a proper review following an operation.

Was there an inappropriate delay between the time of her diagnosis and the date of the operation on her heart?

■ Findings

Once Giddins made a decision to wait to see if Jessica's septal defects would heal themselves, it is unclear if the information essential to determine if this course was working was shared with the Churchill Health Centre, where Jessica was hospitalized.

Her condition did not improve significantly between the time of her diagnosis and her visit to the Variety Children's Heart Centre in February 1994. If anything, there is evidence that her condition worsened. By February 1994, Jessica was diagnosed as having a larger VSD than in October 1993, when she had first been seen. Her shunt had worsened. She was also experiencing congestive heart failure by then and was diagnosed with failure to thrive, a condition closely associated with congestive heart failure.

As was stated in the Caribou case, waiting for a septal defect to close seems to be an acceptable course of action in such cases, and it is hard to fault Giddins for this decision.

However, if the plan was to give Jessica an opportunity to develop further and gain size and strength, not only should such information have been shared with the medical personnel treating Jessica in Arviat, but a plan for that development should have been developed and put into action. That does not appear to have been the case.

Was Jessica's family provided with sufficient information to allow them to give informed consent to the procedure?

As noted, the family declined to participate in these proceedings. Therefore, it is difficult to determine what they felt they were told. From the testimony of Giddins and Odim, it appears that neither the Ulimaumis nor their advisers were informed about problems arising from the previous cases handled by the team; nor were they told about the team's development to that point. The family would have likely been told about the medical issues their child faced, but without further information from them, it is not possible to determine the extent to which they understood what was involved in her treatment.

- Finding

The failure to disclose to the family the surgeon's lack of prior experience with performing operations of this nature without supervision is a matter that repeats itself in this case, as it does in others. Therefore the evidence tends to suggest that Jessica's family was not provided with sufficient information to allow them to give informed consent to the procedure.

Was Jessica healthy enough to undergo an operation?

- Finding

Just before her scheduled operation, an entry in Jessica's medical chart showed that she had been assessed as having had a bout of gastroenteritis—a viral infection. It does not appear that this condition was appreciated before her operation. There is no entry to indicate that the matter of her previous infection had been considered and assessed to determine if the operation should have been delayed. Cornel pointed out that Jessica had also experienced a bout of diarrhea the day before surgery, but she again was not tested for a viral infection before the operation. Symptoms of a pre-operative infection (such as diarrhea) should have led the doctors caring for Jessica to order further tests to determine if she did have an infection. None were conducted. As in the Caribou case, it appears that the doctors' practice at the HSC (of not routinely ordering tests for infection) led to a situation where the existence of an infection was not fully ruled out before a child was sent to surgery.

Did the length of surgery contribute to her death?

- Finding

As noted in the Caribou case, the bypass and cross-clamp times for this operation were very long. The lengthy times and the failed repair contributed to the problems that arose in weaning her from bypass and ECMO.

Were the repairs properly carried out?

- Finding

The evidence clearly suggests that the repair was never successfully done. At least once, and probably twice, Odim failed to properly repair Jessica's defect.

Did irregularities in the process of weaning her from ECMO contribute to her death?

- Findings

The decision to wean Jessica from ECMO seems to have been a necessary one, but the manner in which Odim proceeded was less than acceptable. Odim did not appreciate that the PICU was not adequately equipped to handle any emergencies arising from such a procedure. Odim should not have undertaken the procedure without so determining. He did not ensure that there were appropriately trained and experienced staff, including an anaesthetist, in attendance to assist in this procedure. This fact suggests that he did not carry out this responsibility in a manner that was up to the standards required of him.

However, Kesselman, as the head of the PICU, also had a responsibility to ensure that the child's health was not compromised by such a procedure. In this case, Jessica's health was compromised because the PICU nurses were required to participate in a procedure for which they were neither properly trained nor equipped to carry out, but for which other properly trained and equipped personnel were available.

Odim had every opportunity to request that the procedure be booked in an OR and that the proper complement of staff be present. If the child was not well enough to be moved to the operating room, the OR staff could have attended in the PICU. Odim testified that he was unaware of this, but there is no evidence that he made any inquiries to determine if it was possible to have the OR nurses come to the PICU.

It would appear that Odim proceeded with this matter as he might have in the institutions where he had trained. In his evidence, he suggested that removing patients from ECMO in the ICU was a common occurrence in the institutions where he had trained. That Odim did not know that such practices were not common or successful at the HSC indicates that the entire program started operations in the spring of 1994 without proper preparation.

This was also reflected in the fact that there was a lack of appropriate surgical equipment at the bedside during the weaning procedure. Sending an ICU nurse to look for the Satinsky clamp was necessitated by the poor planning that marked this procedure. The length of time it took for the ICU nurse to find the clamp was a reflection of the fact that she was not trained for this type of procedure and was unfamiliar with the surgical supply room and the type of clamp for which she was looking. This is no reflection on her, because she should never have been put into that position in the first place.

In this case, it also seems clear that there was a tragic failure to clamp the inferior vena cava venous cannula and that this failure contributed to Jessica's massive blood loss and ultimate death. Jessica's condition was severely compromised at the time of the attempt to wean her from ECMO. It is unclear if she would have survived the weaning at all. However, she died due to massive blood loss that occurred through the cannula site and through the unclamped line. It is not clear as to which site caused the greater blood loss, but it is safe to say that both events were preventable.

As noted in the Caribou case, Soder concluded that:

> **[T]he skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations. Surgical factors were the prime determinants of fatal outcome in 9 of the 12 deaths.** (Boldface in original) (Exhibit 345, page 8)

The case of Jessica Ulimaumi was one of the nine that Soder identified in which surgical factors were a prime determinant in a fatal outcome. In particular, he identified the incomplete repair and the decannulation problems as major surgical factors and the lengthy bypass and cross-clamp times as minor factors.

What was the cause of death and was it preventable?

- Findings

Based on the testimony presented at this Inquest, the evidence suggests clearly that Jessica Ulimaumi's death was caused by blood loss resulting in a cardiac arrest. This blood loss occurred during a failed attempt to wean her from ECMO and was the result of blood loss at the cannulation site and the fact that a line was left unclamped during decannulation. However, the underlying cause of death, leading to these problems, was the failed repair.

For these reasons, the evidence suggests that this was a preventable death.

Should this death have triggered a review of the program?

- Finding

This death should have led to a serious re-examination of the program by the persons responsible for it. In his written report to this Inquest, Cornel wrote that the "Death of a patient following repair of a VSD is uncommon and troubling." (Exhibit 353, page 18)

The fact that Jessica died 13 days after Gary Caribou and while Vinay Goyal was seriously ill in the PICU, should have been a warning to Odim, Giddins and their department heads. In his testimony, Cornel was asked if he thought the program should have been reviewed after Jessica's death.

> Yes, I think it certainly is a time for review and reflection and regrouping and all of those things.
>
> When I wrote this original report, I hadn't seen the autopsy specimen and I, you know, I thought, well, this was a VSD that was missed, or the patch came off, and that was troubling by itself, but that is understandable.

> When things go so completely wrong, as I think they did here, I think it really is time to stop and begin again or, you know, reflect and get some outside help if necessary. (Evidence, pages 44,746–44,747)

As the evidence makes clear, many team members were also starting to think along these lines. However, the growing communication problems, coupled with a lack of supervision by senior HSC staff, meant that no review took place at that time.

THE EVENTS OF EARLY APRIL 1994

APRIL 7 – THE CASE OF JM

JM was born on November 8, 1990, and at birth had been diagnosed with complex heart disease. On April 7, Odim performed a hemi-Fontan procedure. JM was returned to the PICU with his chest left open, although covered by a silastic membrane. He was discharged home on April 14.

During the course of the operation, an issue arose between Odim and the anaesthetist involving the use of central venous lines. In the post-operative period, four other issues were identified that led to disagreement and conflict between the PICU staff in general (and Swartz in particular) and Odim. The disagreements centred on pain control, ventilation, antibiotics and the surgeon's monitoring lines. Two other areas of concern noted were post-operative bleeding and pacemaker malfunction. All of these issues were also noted in other cases.

Issues

Central venous vs peripheral lines

Anaesthetists need lines inserted into a patient's veins in order to have a ready route through which drugs and fluid can be quickly administered and to be able to monitor the patient's central venous pressure (the pressure in the large vein leading to the right side of the heart). This helps anaesthetists to ensure that the heart's filling pressures are adequate and that the patient's brain is being provided with an adequate supply of blood.

Such lines are often inserted into veins in the centre of the body, such as the internal jugular vein, and are called central venous lines. Other lines can be inserted into veins in the periphery of the body, such as an arm or a leg, and are called peripheral lines.

Both central and peripheral venous lines can be used to measure central venous pressures. However, using a peripheral vein, such as the femoral vein of the leg, decreases the accuracy of monitoring venous pressure from the central portion of the body. This is important when determining the adequacy of blood supply to the brain. Additionally, the greater the distance the vein is from the heart, the longer it will take for any drug to have the desired effect.

In the case of JM, the anaesthetist inserted a line into the child's internal jugular vein, a vein favoured by the anaesthetists at the HSC. They felt that a central line in the internal jugular was less likely to become dislodged and provided readings of greater accuracy than a peripheral line. Although the anaesthetists could have used the external jugular vein, Reimer said in his evidence that it was more difficult to obtain proper readings from a line inserted into this vein because of the twisting nature of the vein, as well as the presence of valves that could affect the accuracy of the readings. McNeill testified that internal jugular lines were commonplace and used by anaesthetists throughout Canada.

During JM's operation, the internal jugular line had to be adjusted because it conflicted with Odim's planned surgical procedure. This caused Odim to express his concern over the use of central lines. An agreement was reached that internal jugular lines would not be used in patients undergoing pulmonary or Fontan type procedures.

It appears that this issue was resolved in a satisfactory manner. However, the fact that the problem initially arose during the course of an operation is not satisfactory. This was yet another sign that not enough preparation had gone into the restart of the Pediatric Cardiac Surgery Program.

Pain relief

In the PICU, the practice had been to use a continuous infusion of narcotics or analgesia for pain relief. The advantage of this approach was that it provided continuous and even pain relief. Odim preferred intermittent administrations of narcotics. In the JM case, Swartz said that she followed Odim's approach but found that it did not provide stable analgesia. The following day she spoke to Odim about this issue. Swartz testified that Odim wanted to see any papers or articles that backed up her point of view. She recalled offering to provide them if Odim was serious in his request. She said he did not ask for them and she did not provide them. From that point, the staff in the PICU provided pain relief in a continuous, rather than an intermittent, fashion.

Ventilation

Another practice in the PICU had been to have children breathing on their own as soon as possible after an operation. Odim preferred to keep the patients' muscles fully relaxed with anaesthetic drugs until their chests had been closed, which meant that they would have to be artificially ventilated. Odim wanted JM to remain intubated and ventilated overnight. Reimer, who was the anaesthetist for the operation, had not known of Odim's preferences. Instead, he had anaesthetized JM in a manner that conformed to past practice. According to Reimer's testimony:

> This child was basically left with a Fontan type of circulation. And with this type of circulation it is actually hemodynamically advantageous to have spontaneous breathing, that is for a patient not to be on a ventilator. And spontaneous breathing is better because pulmonary vascular resistance is lower and blood flow through the lungs is better than with controlled ventilation.
>
> So my anaesthetic technique for this child was actually tailored in such a fashion as to allow early resumption of spontaneous ventilation at the end of this procedure. And so I had done that, the surgery was done, and at the end of the procedure Dr. Odim's opinion was that this took quite awhile, I think we should just sedate the child and ventilate him over night. And the intensivist's opinion was, look, we can re-establish spontaneous ventilation and extubate this child today. (Evidence, pages 18,795–18,796)

As a result, JM began to breathe on his own, shortly after returning to the PICU. Odim requested that Swartz keep him intubated and ventilated. She did not follow this approach, although she did provide him with intermittent pain relief (Evidence, page 15,343).

Antibiotics

In addition to these two concerns that were identified during the JM case, the PICU staff were also concerned about Odim's use of antibiotics. The practice in the PICU had been to discontinue the administration of antibiotics after 24 hours, unless there were signs of infection. The reason for discontinuing the antibiotics was to reduce the possibility of the patient developing organisms that were resistant to the antibiotic. Odim preferred to continue to administer antibiotics until all lines had been removed from the child. In this case, the PICU staff provided the antibiotics as Odim requested.

That Odim would have different approaches to these issues is not unexpected. Furthermore, this Inquest is not in a position to adjudicate between these approaches. However, the fact that these differences emerged during patient care is a sign of the failure to prepare properly for the relaunch of this program.

OTHER PICU ISSUES

Surgical monitoring lines

A more serious issue continued to revolve around the monitoring lines that Odim employed. These lines could be used both for monitoring the patient and infusing drugs. (This was the issue that Feser had first raised with Odim at the PICU meeting of March 22.) Where Duncan had used lines that came as a single component, Odim constructed his own lines and sutured them together. According to Swartz, these lines would fall apart in the ICU.

> And that would mean that the patient—that the patient was exposed or the heart—the inner chambers of the heart were exposed to air, and this can be lethal. (Evidence, pages 15,327–15,328)

On the same issue, Reimer testified that post-operative monitoring was also hindered because the transthoracic lines that Odim placed frequently came out of the heart.

> The way that they were usually placed was they would be put through the wall of the heart and then tied into place with a suture. When they are tied in, obviously, the suture has to be adjusted so that it's tight enough to hold the line and not too tight that it occludes the line. But, for whatever reason, they came out on a not infrequent basis. (Evidence, pages 18,902–18,903)

Concern about the transthoracic lines was also expressed by Barwinsky, who occasionally looked after Odim's patients if he was out of town. In April, Barwinsky closed the chest of a child (CSM) who had undergone removal of a pulmonary artery band and other repairs of a complete AV canal defect. According to Swartz's testimony, Barwinsky was concerned that the monitoring lines, rather than emerging through a separate opening point, came out through the surgical wound. He was concerned when he was closing the chest that he would block or dislodge these lines.

Swartz said that she never spoke to Odim about the issue of the transthoracic lines. However, she said that Kesselman did. When Kesselman spoke with Odim about this issue, he relayed the concerns that a number of nurses had expressed about the problems with the lines. He testified that he told Odim to be more careful when constructing the lines. However, Kesselman said he could not tell Odim not to construct his own lines. Despite this conversation, Kesselman said that Odim did not change his approach to the monitoring lines. The PICU staff resorted to using wooden sticks, similar to tongue depressors, to reinforce the joints in the lines.

Post-operative bleeding and pacemaker malfunction

In addition to these concerns, the PICU staff noted that the level of post-operative bleeding in Odim's patients was higher than they would have anticipated. Dr. Walter Duncan testified it was important not to transfer a patient from the operating room to the ICU until the patient was stable and bleeding had stopped. This had been the approach followed by Dr. Kim Duncan when he had been the surgeon in the Pediatric Cardiac Surgery Program. However, Odim felt that patients recovered best and bleeding could be better addressed in the ICU, and he felt it was important to move the patient from the operating room to the ICU as soon as possible. Therefore the patients that Odim sent to the ICU suffered more bleeding than the ICU staff had expected. This difference was also one that could have been addressed during the startup phase of the program earlier in the year.

APRIL 13 – THE CASE OF CSM

CSM was born on January 15, 1993. Shortly after birth, she was diagnosed with Down's syndrome and a complete AV canal defect. On June 3, 1993, she underwent a palliative banding of her pulmonary artery. (In this procedure a band is placed around the artery to reduce the excess flow of blood through the artery.) After that, she had had frequent bouts of pneumonia, with recurrent wheezing and increasing fatigue on activity.

On April 13, 1994, CSM underwent a procedure where the band was removed from the pulmonary artery and other repairs to her heart were carried out. She underwent CPB for five hours and fifteen minutes and had a cross-clamp time of two hours and fifty-eight minutes.

Her chest was left open for 16 days in the PICU and she required a temporary pacemaker. CSM had problems with her mitral valve, resulting in mitral regurgitation (blood flowing the wrong way through the mitral valve). She also had problems with congestive heart failure and recurrent infections. There were difficulties in weaning her from the ventilator, and she had a prolonged need for inotropic support. She spent 62 days in the PICU and was discharged on June 26, 1994. These times represent a lengthy period of bypass and a lengthy stay in the PICU. Odim agreed that her lengthy bypass time, in addition to the long cross-clamp time, might have hindered her recovery.

While in the PICU, CSM also suffered from junctional ectopic tachycardia (JET), an abnormal heart rhythm with a very rapid heart rate. This condition can be fatal if not properly controlled. There were differences of opinion among the doctors as to how this condition should be treated. This conflict revealed that Odim had not yet understood the protocols regarding the ordering of medications in the PICU.

According to Kesselman, Giddins, after discussions with Odim and Kesselman, suggested that the JET be treated with propafenone, a drug not widely used at the HSC. Odim wanted to use another drug, Pronestyl (also known as procainamide).

Propafenone was not immediately available in Winnipeg. The testimony presented to this Inquest differs as to the way in which events then unfolded. According to Kesselman, propafenone was acquired, but did not prove effective. At that point CSM was treated with Pronestyl, as Odim had suggested. According to Odim's testimony, his orders were overruled by the PICU doctors, who administered Pronestyl only when he put his "fist down".

> My recommendation to use a particular drug was not followed for a 24 to 36 hour period while the patient was simply getting worse and worse to the point that I had to at the end of one of our pre-operative conferences, after I had come back to discover that nothing had been done, talk to the team.
>
> The intensive care doctor at the time felt that in her experience a certain drug was better but that drug was not in the hospital and I said well, if you don't have the drug and we have Pronestyl in the hospital why are you not giving this child this drug who we may lose while you are waiting to get this experimental drug from Ottawa. I was overruled. They got the drug from Ottawa the next day and give it enterally or through an NG tube, so they gave a drug that's supposed to be given intravenously for a condition, they were giving it through the GI tract and at a subminimal dose.
>
> At that point, I simply had to put my fist down, the Pronestyl was given and within 24 hours the child turned around. So that's an example of a reluctance to—because of turf issues, to follow the lead of the surgeon. (Evidence, pages 26,402–26,403)

It should be noted that propafenone was administered in the manner prescribed by Giddins.

The testimony of Dr. Fiona Fleming, the intensivist caring for CSM during this period, differed from Odim's. When Fleming took over treatment on Sunday, April 17, the HSC staff were not aware of the fact that propafenone was not easily acquired. Fleming testified that when she examined CSM the next day, she discovered that earlier that same morning Odim had written an order calling for treatment with Pronestyl. She testified that she consulted with both Odim and Giddins about Odim's order. The conclusion of this consultation was an understanding that CSM would be treated with propafenone. Fleming said it was not a unilateral decision on the part of the ICU doctors, but rather the result of a discussion between herself, Odim and Giddins. She also testified that all orders written on the charts had to be signed by the ICU staff intensivist. When the propafenone arrived and failed to bring about an improvement, Fleming testified, after a further consultation with Odim and Giddins, a decision was made to use Pronestyl.

In commenting on Odim's description of the event, Fleming testified that she did not believe the issue was one of turf but one of communication.

> That my understanding was the course of action had been agreed upon, and that Dr. Odim had decided he wanted something different, which in retrospect turns out to be the correct drug, but it was left on the chart, with no telephone call to myself, no conversation to my resident, and I don't know whether he or Dr. Giddins discussed it between themselves. But certainly when I discussed it with Dr. Giddins later that morning, he said, no, we are going to use propafenone. (Evidence, pages 35,996–35,997)

As Fleming noted, it appears that the drug that Odim wished to use in treating CSM was more effective. However, it also appears that he had not familiarized himself with the PICU protocols. It also appears that he did acquiesce to the use of propafenone which, according to Fleming, was the drug preferred by Giddins.

Odim testified that it was only after this case that he came to understand that he could not write medication orders for the patients in the PICU. While he said that this concept was new to him, evidence from

Feser suggests that this had been brought to his attention in February at their initial meeting and again at a meeting on March 22. At this second meeting, it appears that Feser had spent a considerable amount of time discussing this issue. Either Odim wilfully refused to adapt to the PICU practices or he simply did not pay attention to important information that the nursing staff presented to him. Neither possible explanation speaks well for him.

On April 18, the PICU senior team leaders held a meeting. According to notes taken at the meeting by Feser, one of the issues discussed was that of Odim's attempts to prescribe medication to patients in the PICU. According to Feser, there were a number of problems that arose out of Odim's apparent lack of regard for the PICU protocol. In some instances, Odim would speak to the PICU nurses in the morning to discuss how a patient had done overnight. During these conversations, he would tell the nurse to change some aspect of the patient's medication. However, the nurses were not supposed to make any changes to a patient's medication that had not been ordered by an intensivist or an ICU resident. In addition, Odim would give orders directly to nurses at the bedside. Feser testified:

> In fact, you know, by this time he is also, he is getting annoyed because he is asking, like why wasn't this done, because I had asked for this to be done. Where he is not really, he may have mentioned it to the bedside nurse or asked it, but he has not relayed that in full detail to the resident or the intensivist. So we are wondering, what are we supposed to be doing? Are we going to maybe change what we have been doing in the past? (Evidence, pages 29,989–29,990)

This problem continued throughout the year.

VINAY GOYAL — THE SECOND PROCEDURE

CONSENT FOR THE REOPERATION

Vinay Goyal was rescheduled for surgery on April 6, 1994. According to Sheena Goyal, the family did not feel that it had any options when consent was requested for this procedure. She testified, "We had no, nothing, anywhere else to turn to, nobody else to turn to. So we had no choice." (Evidence, page 978)

DELAY IN THE SECOND OPERATION

However, the operation did not take place on April 6. It was delayed for two weeks so that Vinay could recover from a viral infection. From Sheena Goyal's testimony it appears that Vinay was tested for this infection largely at her insistence on April 5.

> That day I was very concerned, like my whole family was very concerned. Like he was going for the surgery and nobody even noticed that he had that cold and that could have serious infection. (Evidence, page 972)

According to her testimony, a female doctor in the PICU eventually ordered a number of tests that led to the postponement of surgery. The doctor she spoke with was Swartz. In her testimony Swartz said:

> This is the perfect season for this particular virus which is called RSV, which is respiratory syncytial virus, which is not a friend to patients with congenital heart disease. And the concern is going in

> for—being on bypass with RSV is essentially lethal, which might also explain why his lungs were a bit leaky and why we were having trouble with ventilation. (Evidence, pages 15483–15484)

After discussing the matter with Sheena Goyal, Swartz ordered a new RSV test. (A previous one a few days earlier had come back negative.) Swartz then spoke with Odim and suggested that the operation be postponed. According to Swartz, Odim initially opposed this suggestion because he believed that it was necessary to repair the heart as soon as possible. In the morning, the RSV test results came back positive and the procedure was postponed.

In his testimony to this Inquest, Cornel commented on the prospect of re-operating 30 days after the initial operation.

> It's just about the worst time to have to re-operate. The adhesions at this stage are kind of a bloody, gelatinous mess that glue the heart and its structures, its surrounding structures together, and, obscure the details of the anatomy.
>
> Wherever you dissect to free the heart from the other structures bleeds—not a huge amount of bleeding, but it's all oozing all the time. It obscures where you want to work, makes it difficult to work. It makes accurate dissection very difficult.
>
> It's, it really is a horrible time to have to go back. (Evidence, page 44,761)

Cornel also testified that he believed that redo operations, particularly the management of the adhesions that form following previous operations, are very difficult. He said the management of such adhesions is a skill that surgeons only develop over time.

> You do hear or do see people say in the surgical literature that re-operation adds no risk. I think they are just being macho about it. I just don't believe that it adds no risk. It certainly adds huge trouble and time. And re-operating at a month, I think adds more risk than at, say, a year after surgery. (Evidence, page 44,763)

Odim disagreed. In his testimony he said that re-operating 30 days after the original operation was not necessarily the worst time. Odim said that the time range for having these difficulties with re-operations was between three weeks and two to three months after the first operation.

Frankly, Cornel's evidence is to be preferred to that of Odim on this point. Cornel was a surgeon of considerably more experience than Odim and was much more familiar with actual day to day issues than Odim was. This was the first time that Odim had had any experience with doing a redo 30 days after an initial repair on his own, and his comments suggest more bravado than experience. It also appears, however, that Vinay's condition at this point had left the surgical team with no other option.

PRE-OPERATIVE STATUS

In her pre-operative assessment on the evening of April 17, Swartz summarized the various problems Vinay had had. She wondered if he had had an RSV pneumonia. She noted that he had a sore under his chin that had not healed. Swartz said there was increased risk for surgery because of the problems that Vinay was experiencing. In addition, she said that he could have difficulty with his heart rhythm (as during the first repair), potential heart failure as a result of a long pump run, bleeding as a result of the fact that this was a re-operation and aggravation of kidney problems. She assigned him an anaesthetic class of ASA IV.

THE OPERATION—APRIL 18

The surgical team involved in the second operation is set out in the chart.

TABLE 6.7 : Persons involved in the operation on Vinay Goyal, April 18, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistants	B.J. Hancock, S. Wiseman (resident)
Anaesthetists	J. Swartz , A. McNeill
Scrub nurses	C. Youngson, C. Weber, C. McGilton
Circulating nurses	S. Scott, B. Zulak, A. Glenday, W. Yakinchuk
Perfusionists	T. Koga, M. Maas

TABLE 6.8: Length of phases of the operation on Vinay Goyal, April 18, 1994

Phase of the operation	*Time taken*
Induction	2 hours 20 minutes
Bypass	4 hours 14 minutes
Aortic cross-clamp	2 hours 2 minutes
Total surgical time	7 hours 50 minutes
Total operating-room time	10 hours 40 minutes

Prior to Vinay being taken to the OR, a disagreement also arose between Swartz and Odim over whether Vinay's lines should be changed in the ICU. In the end, Swartz prevailed and new lines were inserted. Swartz testified that during the discussion she had had with Odim, he told her that she had a lot of testosterone, a remark that led her to terminate the conversation.

The operation on April 18 revealed that there were patch leaks beneath the aortic valve and at the ventricular crest. These were repaired. In their report, Cornel and Duncan commented that this was a lengthy operation.

INTRA-OPERATIVE INCIDENTS

A number of incidents arose during this operation that deserve mention. These included the apparent dribbling of adrenalin on Vinay's heart, the testing of the patch by the forceful injection of saline into the heart chambers and the early removal of a cannula.

Dribbling of adrenalin on the heart

After the repair was done and before Vinay was weaned from bypass, Odim wanted to infuse adrenalin from a syringe through a line directly into Vinay's heart. According to several of the witnesses, including Swartz, Irene Hinam and the operating-room nurses, after administering some adrenalin intravenously to

Vinay, Odim dribbled the adrenalin remaining in the syringe onto the heart. Almost immediately, the heart changed color and contracted violently, creating noticeable changes in Vinay's blood pressure readings. These changes were noted on the anaesthetic record, as was the event. The other team members were surprised by this action. Swartz said this was something that she had never seen before and questioned the wisdom of doing such a thing to such a fragile heart. When Swartz asked why he did it, Odim asked—in what she interpreted as a sarcastic tone—if he should have thrown the rest of the drug on the floor instead.

Odim's recollection was different. He said that he decided to give the adrenalin into the heart through the intracardiac line to ensure that it was in a blood vessel. He said that Swartz was upset at this, but followed Odim's request. Swartz denied being upset, saying that she was familiar with the technique of infusing adrenalin directly into the heart. Odim said that once the blood pressure went up, he told Swartz to turn off the epinephrine (adrenalin) drip. Odim said that it was not uncommon to see a quick rise in blood pressure when one treated a patient with adrenalin in this way. He did not recall dribbling the adrenalin directly onto Vinay's heart. He did not, however, deny that it happened.

Hinam also testified that Odim put adrenalin straight on to the heart, making the heart turn colour, and causing the blood pressure to rise dramatically.

The testimony of the several witnesses, as well as the clear indication on the anaesthetic record of this incident, is convincing evidence that this incident occurred as the witnesses said it did. Why Odim did what he did is unfathomable. It is possible that he was simply interested in observing how the heart muscle would respond to such an event. There was certainly no medical reason for it.

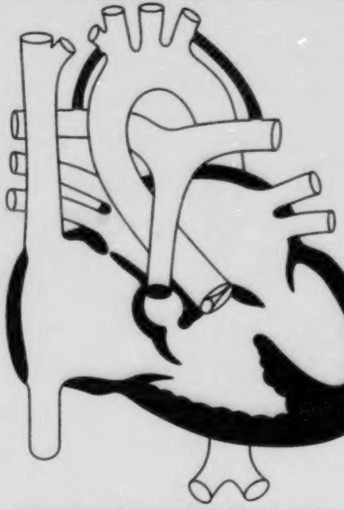
Testing the patch

After he had repaired the patch leak, Odim performed a test of the patch repair that took the team by surprise. Youngson, Swartz and Hinam testified that Odim took a syringe filled with saline and injected the saline into the heart with considerable force. Youngson said that Odim pushed the saline into Vinay's heart through the syringe with the heel of his hand. They were all shocked by the intensity of the procedure. Youngson testified:

> Because, first of all, we had just done a repair inside of this heart, what is that going to do to the repair, first of all? And secondly, there is lots of very delicate tissue, and this heart is very kind of friable, kind of mushy, the tissues aren't very strong. And to me that seemed like, it didn't seem like a very good thing to do. (Evidence, pages 8,398–8,399)

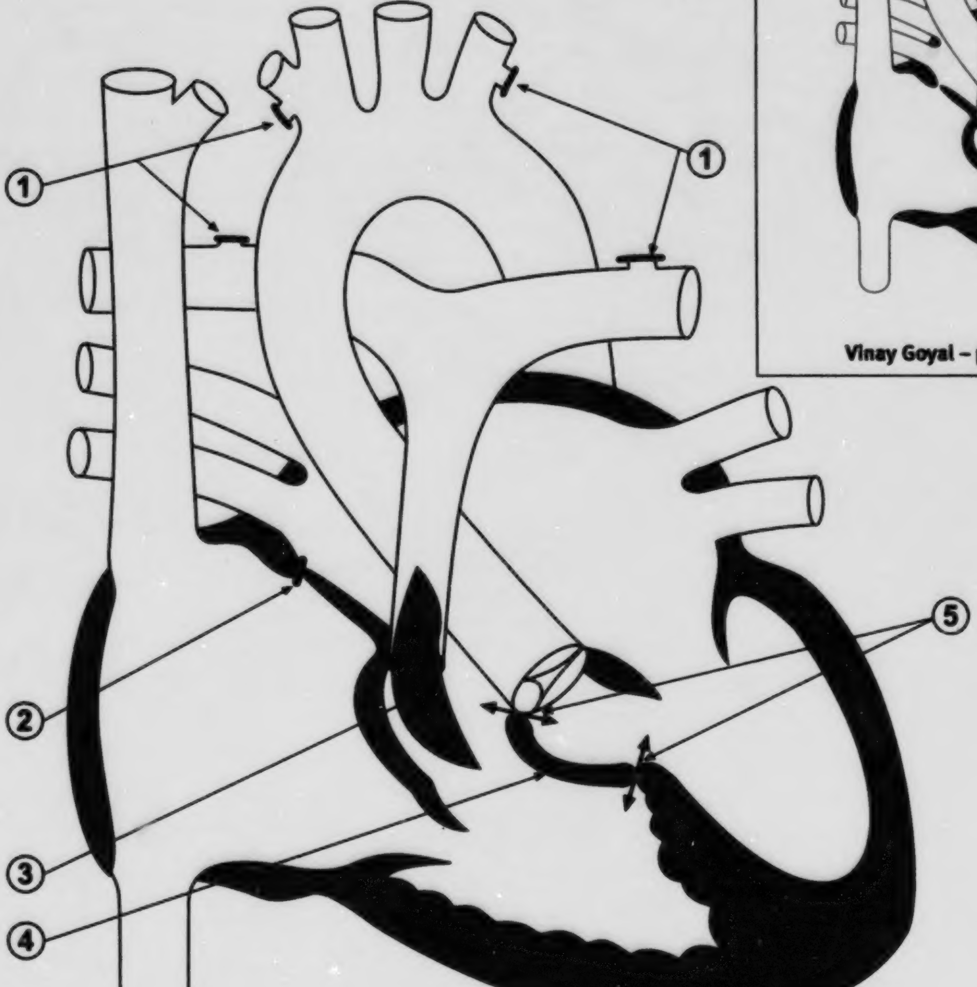
Swartz said that Odim pushed the syringe with as much force as he could, and she was concerned about that tearing the tissue. She had never seen this method of testing the integrity of a patch and was concerned by the amount of force he was using and that it might damage the heart. She testified:

> I was unfamiliar with this method of assessing integrity of the patch. But I was also concerned at the time that he was using a lot of force in injecting relatively, as he said to me, blindly. And I didn't know where—you would imagine that the saline would come out at a very high pressure and that the chances of damaging the heart enters one's mind, and that thought came into my mind. (Evidence, pages 15,542–15,543)



Vinay Goyal – pre-operative heart

Diagram 6.7 Vinay Goyal – post-operative heart



1 – Takedown of Blalock-Taussig shunts

2 – Suture closure of patent foramen ovale

3 – Pulmonary valvectomy and transannular right ventricular outflow tract patch, with resection of right ventricular muscle bands.

4 – Patch closure of ventricular septal defect

5 – Patch site leaks

Odim testified that he administered the saline from a syringe attached to a red rubber catheter inserted into the left atrium. He wanted to see if the saline would appear on the right side of the heart. Odim said that he did not have any concerns about injuring any of the tissue by using this technique to test for leaks. He said that the tissues of the heart were probably not more friable (fragile and easily torn) at 30 days after the first operation. Odim said he didn't think this method led to tears. In his operative report, he said that the left side of the heart was filled vigorously with cold saline. By vigorously, Odim said, he meant a firm squeeze of the syringe's plunger because the red rubber catheter attached to the syringe provided a resistance that had to be overcome.

Soder said that he had seen this technique done with some frequency to test a patch repair, although he could not comment on the degree of force used.

The premature removal of a cannula

After being weaned from the bypass machine, Vinay was in unstable condition and was bleeding from the chest wall cavity. There was disagreement between Swartz and Odim as to whether or not the bleeding was due to a coagulopathy or to a surgical cause. This led to a series of dramatic, and eventually tragic, events.

A coagulopathy is treated by giving a patient various blood products, thus helping the patient's blood to clot properly and stop bleeding. Swartz said that normally when a patient was treated with blood products, clots formed. She said that the sequence of bleeding without clots, followed by the presence of clots after the administration of blood products, showed that the patient had a coagulopathy and that it was resolving. However, if the bleeding was coming from an operative site that had not been completely sutured, the bleeding was termed 'surgical', and it was necessary to find the leak and repair it. In Vinay's case, the bleeding continued despite the administration of clotting drugs. For this reason Swartz thought that there was a surgical bleed.

While Odim was searching for the leak, Swartz asked Maas to transfuse blood into Vinay through the aortic cannula to compensate for the loss of blood and maintain Vinay's blood pressure. At that point an alarm went off, indicating that there was a blockage in the cannula through which Maas was attempting to deliver blood. When Maas asked what was wrong, Odim informed him that he had removed the cannula through which Maas was trying to transfuse blood.

The fact that the aortic cannula had been removed came as a surprise to almost everyone in the OR. Odim testified that he had announced that he was removing the aortic cannula. Koga, one of the perfusionists, recalled Odim saying the aortic cannula was out but could not recall him informing the team before removing it. Hancock testified that she vaguely remembered going through the sequence of removing the cannula. From the testimony, however, it appears that none of the nurses, the anaesthetists or the other perfusionist knew that the line was out.

Youngson had no memory of assisting Odim to remove the cannula. She testified that Swartz told Odim that he should not have taken the cannula out without telling her. Maas appeared confused as to what was happening. In his testimony, Maas said he could not recall being told the cannula had come out. Maas testified that typically the perfusionist and the anaesthetist were made aware that the aortic cannula was going to be taken out. He said that in Vinay's case they were not told that it was going to be or had just been removed, and they learned that it was out only after the fact.

The removal of the cannula greatly compromised the anaesthetists' and the perfusionists' ability to keep up with Vinay's blood loss, since other lines that the anaesthetists could use to transfuse blood could not provide the same volume of blood as the one Odim had removed. Swartz, McNeill, Maas and Hinam struggled to find another way to transfuse Vinay because it was not possible to reinsert the cannula. In addition, removal of the aortic cannula meant that it was not possible to transfuse Vinay with the blood products still present in the bypass machine. Instead, a member of the team had to leave the OR to get additional blood products.

Normally, in the decannulation process, the aortic cannula is the last one to be removed. This is precisely because it is kept in place in case it is needed for transfusing large amounts of blood to the patient. All of the available evidence compels the conclusion that Odim removed the cannula from the cannula site on his own, without warning the other members of the operating team that he was doing so. In removing the cannula, he severely compromised the team's ability to transfuse blood to the patient, who was losing blood at an alarming rate.

Furthermore, it was not appropriate to remove the cannula until the existence of a surgical bleed had been ruled out. Eventually, Odim did in fact discover that there was a surgical bleed (a tear in the heart) and sutured the defect. Odim testified that he did not know how the tear in the heart had occurred.

Unfortunately, the repair of the surgical bleed occurred too late for Vinay. His blood pressure did not recover after the bleeding was controlled and he quickly deteriorated to the point of cardiac arrest. Vinay was pronounced dead at 1907 hours in the OR.

Odim said that at the time he took out the cannula, it seemed that the problem they were dealing with was a coagulopathy. His evidence, that he believed he had told the team that he was going to take out the cannula, is difficult to accept, given that every other person in the room, except for Hancock, was certain that he had not.

Odim admitted that Vinay's death could have been prevented if they could have kept up with the blood loss. The loss of the cannula directly contributed to the team's inability to transfuse blood properly.

There were no incident reports filed on any of the events that took place during the second operation. Swartz testified that she had written a note about the incident concerning the removal of the aortic cannula, but she admitted that she might not have placed the note in the chart. She was unable to locate the note.

No member of the HSC staff made use of the incident report system to flag any of the issues. Indeed, it is distressing that many staff members did not even believe that the reporting system applied to them.

When questioned as to why she had not filed a report, McNeill, who witnessed the events, testified, "I wouldn't—I didn't write an incident report, and even in my practice now I wouldn't, because I don't sort of consider—I don't consider it a tool that I use." (Evidence, page 13,179)

Swartz testified that within 15 minutes of Vinay's death, she spoke to Odim and asked him why he had taken the cannula out and why he had failed to inform people that he was taking it out. She testified that Odim explained that he had taken it out because he was worried about problems with clotting. In addition, he acknowledged that there had been communication problems in the OR.

Shortly after surgery, McNeill also asked Odim why he had removed the cannula. In her testimony she said that she found Odim's explanation unsatisfying. She testified that:

> the whole experience was unsettling and was, I don't know how more to say it. I just didn't, I didn't feel that we had sort of dealt with it, or that we had adequately, or that I adequately understood why and how it all happened. (Evidence, page 13,181)

This dissatisfaction led her to take her concerns to her section head, Dr. Suzanne Ullyot.

Odim testified that the case was discussed at a subsequent Morbidity and Mortality Round. He said he concluded that Vinay might have been saved "if we had been able to keep up with the coagulopathy and the blood loss." (Evidence, page 24,603)

AUTOPSY

Since the family objected on religious grounds to the hospital's request for an autopsy, no autopsy was performed.

FINDINGS

As noted earlier, the following issues arise in this case:

- Were Vinay's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Would Vinay have been taken to surgery with a potential infection if his parents had not intervened?
- Did the surgeon demonstrate the skills and experience necessary to undertake this high-risk surgery?
- What was the cause of death and was it preventable?

Were Vinay's parents provided with sufficient information to allow them to give informed consent to the procedure?

- **Findings**

In the fall of 1993, the family was initially offered the opportunity to take their child to another heart centre. However, they were persuaded not to do so after it was determined that Odim would be arriving early in 1994. They seemed inclined to have the operation done in Winnipeg if it could be done here.

It is clear from the evidence that the Goyals were made aware of the major medical issues facing their child. However, it is also clear that neither Odim nor Giddins informed them about the level of Odim's surgical experience or the death of Gary Caribou.

It is difficult to say whether or not the Goyals might have consented to Odim performing the operation even if they had been aware of his lack of experience. But that issue is irrelevant to the question of their entitlement to receive an accurate answer to their query. Sheena Goyal had

clearly asked Odim what his experience was in doing this type of operation, and he was less than forthright in telling them of his lack of experience. This evidence tends to suggest that Vinay's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Would Vinay have been taken to surgery with a potential infection if his parents had not intervened?

- **Finding**

The operation that had been scheduled for April 6, 1994, had to be delayed because Vinay had an existing infection. The evidence suggests that the infection was discovered only after Sheena Goyal insisted that the team check for one—an alarming prospect, given the position of the VCHC on the danger that infections presented to children having heart surgery. This delay was appropriate, however, given the knowledge of such dangers, although it likely contributed to additional risks for Vinay's second operation. Swartz's ordering of tests to check for an infection was appropriate, but Odim's resistance to delaying the operation pending such tests was not. Additionally, it is noteworthy that despite the clear evidence of an infection, Odim seemed to be of the view that there was nothing to be concerned about.

Did the surgeon demonstrate the skills and experience necessary to undertake this high-risk surgery?

- **Findings**

The failed repair from the first operation seems inexplicable. It is difficult to understand why Odim was unable to repair the heart defect properly. The procedure was not beyond the capabilities of an experienced surgeon. However, it cannot be overlooked that Odim was not an experienced surgeon, nor did the team have much experience in dealing with cases of any complexity.

The decision to re-operate on Vinay's heart 30 days after the initial operation was probably the only option remaining. It was obvious that the initial repair was unsuccessful and that without a re-operation, Vinay would likely die. It would also seem that Vinay was not in any condition to be transported any distance, although there was a possibility that another surgeon could have been brought to Winnipeg to perform the operation.

The events of the second operation include behaviour on the part of the surgeon that causes one to question his ability to perform these types of operations in an unsupervised setting. His action in dribbling adrenalin on the heart was foolish and potentially dangerous.

But the most serious action was that of removing the aortic cannula without properly preparing the team. The weight of the evidence suggests that proper notification was not given before the removal of the cannula. The removal of the aortic cannula during the critical and lengthy search for the cause of Vinay's bleeding contributed directly to this child's death. Removal of the aortic cannula compromised the team's ability to transfuse the child appropriately and caused them to fail to keep up with Vinay's blood loss. Vinay bled to death on the operating-room table. The evidence suggests that if the aortic cannula had been in place, the surgical team would have likely been able to keep up with his blood loss until the surgical bleed had been discovered.

As noted in the Caribou and Ulimaumi cases, Soder concluded that:

> **[T]he skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations. Surgical factors were the prime determinants of fatal outcome in 9 of the 12 deaths.** (Boldface in the original) (Exhibit 345, page 8)

The Goyal case was the third in which Soder identified major surgical factors leading to a patient's death. In this case he identified the incomplete repair in the first operation as a major factor, while the prolonged bypass and cross-clamp times in both operations were minor factors, as were the excessive bleeding and cannulation difficulties in the second operation. Soder indicated that the late decision to operate on the residual VSD was also a major factor.

What was the cause of death and was it preventable?

■ Finding

Vinay died due to bleeding during his second operation. The evidence suggests that this was a preventable death.

At this time in the program's history, three children had died, partly because the surgeon did not have sufficient skills to undertake the planned repairs. As the events recounted to this point in the narrative make clear, the program had been restarted and difficult procedures had been undertaken with insufficient planning. Three of the outcomes to this point were tragic. If there had been appropriate monitoring and review of outcomes, by this time, the program would have been subjected to a review, even if one had not been called after the case of Jessica Ulimaumi.

REACTION OF THE PCS TEAM FOLLOWING THE DEATHS OF GARY CARIBOU, JESSICA ULIMAUMI AND VINAY GOYAL

Vinay Goyal's death had a significant impact on many of the people who had been involved in his case. Feser testified that she recalled walking into work on the morning after Goyal's death and seeing his empty bed. She assumed at first that he had been moved to another ward. When she was told what had happened to him, she said she cried.

> In fact, I had to turn around, go back to my office, and do what I am doing now, had a good cry. And I came back to the unit because I had to come back and listen to, I wanted to know the details on what happened and I would go in to report. And I still to this day keep thinking, you know, that boy should not have died. (Evidence, pages 29,952–29,953)

Swartz testified that she felt that she and other members of the team, specifically McNeill, Hinam and Youngson, were shocked by the death of Vinay Goyal.

The deaths of three children in such a short period of time would have been unsettling for any pediatric cardiac surgery program. As suggested above, these deaths and the circumstances surrounding them ought to have led to a review of the program. The fact that no such review was ordered was a source of real concern for many of the people involved in the program, particularly the nurses and the anaesthetists. By this point, they had concerns about Odim's skills, both as a surgeon and as a team leader. Such reservations, unless expressed openly and directly, can be poisonous for a team.

Because of their concerns, by April many members of the team were trying to attract the attention of those in some position of authority in the hope of instigating a review of the program. The anaesthetists were eventually able to trigger a reduction in the program's activities in May 1994.

THE RESPONSE OF THE NURSES

Many of the nurses were developing reservations about Odim's surgical techniques and their impact on patients. Youngson testified about these concerns at length before this Inquest.

> There were other things going on, other cannulation problems, other bleeding problems, or just technical things that were happening in the operating room on sort of the routine case that we were doing, you know, on the kids that are still alive. (Evidence, page 8,385)

Youngson also felt that Odim exhibited unnecessary roughness while undertaking cannulation during these early operations.

> Well, he would be trying to put in a cannula, and I felt that he was very rough, his technique was very rough. He seemed to want to get that cannula in no matter what. And on occasion I would sometimes feel that the cannula was maybe too big for this particular vessel, or some concern like that.
>
> Occasionally, he would tear the purse string, so that when the cannula was in and you went to snug up the wall of the vessel around it, you couldn't do that, and then you would be faced with a bleeding situation again. And these sorts of things were happening on an ongoing basis. We would have to repair these vessels, we would have to redo the purse strings. (Evidence, pages 8,385–8,386)

Youngson said that the roughness also extended to the manner in which Odim would handle the children's hearts. She said that she was not used to a surgeon who touched and prodded the patient's heart as much as he did.

During the Inquest, Youngson was asked why she did not take these concerns up with Odim directly. She gave the following answer:

> Historically and traditionally, when nurses have a serious concern, and I'm not just talking about a little fight that you might have had with a surgeon in the OR, but a serious concern about competency, for instance, you go through what are considered the proper channels.
>
> My understanding of that was to go to my head nurse, and then go to the director of nursing. (Evidence, pages 8,775–8,776)

Youngson followed just such a course. At first she raised her concerns informally, speaking with Dixon during their regular workday encounters about her early concerns with Odim's problems with cannulation.

Dixon recalled meeting with Youngson and other nurses after the Ulimaumi case. She testified that the primary concern they voiced was that there did not seem to be anyone in a position of authority who was aware of what was going on. She and the nurses decided to see what they could do to get someone in such a position to take an interest in what was happening.

Borton began to have a number of doubts about the program following Jessica Ulimaumi's death. Her concerns increased during the spring.

After the death of Vinay Goyal, Youngson again went to speak with Dixon about her concerns. Dixon suggested that she speak with nursing director Isabel Boyle, and a subsequent meeting took place between Boyle and Youngson.

Hinam testified that in April a number of nurses approached her with their concerns about the program. These nurses included Feser, Plouffe, Armitage and Kiesman. She said they were concerned about the amount of post-operative bleeding in patients in the pediatric cardiac program. They also expressed concern about the fact that patients were having their chests closed in the intensive care units, rather than being taken back to the OR. While Hinam had concerns about what she had witnessed in the OR, she told the nurses that she thought they ought to give Odim a chance. However, Hinam testified that Odim seemed to have continuing problems with cannulation and operative procedures:

> How to hook everything up and how to put everything together, clamps not being taken off when they should, cannulas coming out, bleeding, long pump times, long circulatory arrests. There was a lot of things in the OR that were raising red flags. And you thought, is it just me or is everybody seeing this? (Evidence, pages 11,484–11,485)

Hinam and Youngson both recalled that they met with Boyle more than once during April 1994. On April 28, after the death of a fourth child, Daniel Terziski, Hinam and Youngson met with Boyle to outline their concerns. According to Hinam, Boyle indicated that she would speak to Bishop about this issue. Furthermore, Boyle told Hinam that she should continue to encourage other nurses to give Odim the benefit of the doubt. Youngson once again relayed the concerns that the nurses had over the results in the pediatric cardiac program and the effect that the deaths of the children were having on her and her colleagues. According to Youngson's testimony, Boyle agreed to ask those in charge of a special program in the hospital called the Critical Incident Response Team to meet with the nurses in order to assist them in dealing with the emotional impact of the series of deaths. In her testimony, Hinam said that at one point in the meeting with Boyle, both she and Youngson were in tears.

Following the meeting with Boyle, Hinam and Youngson discussed the question of making notes about what they had witnessed and heard. Hinam recalled:

> I said to her that she should start making notes. I said, you know, you are the one that's right there, I'm in and out, I don't see it, but you are right there. And I said, one of these days, one of these days this is not going to be an aboriginal child, this is not going to be a child from up north, it is going to be an upper middle class white family that has the ins into the medical system and is going to know that this shouldn't have happened, and there is going to be a lawsuit, and I think you should chart about it, because you are going to be called for sure. (Evidence, pages 11,485–11,486)

The point that Hinam was making deserves comment. The first three children who died in 1994 were children of visible-minority families. Caribou had been a member of Mathias Colomb First Nation, Jessica

Ulimaumi had been an Inuk child from the Northwest Territories (now Nunavut), and Vinay Goyal had been the son of an East Indian family. The order in which their cases had been selected appears to be nothing more than coincidence. However, their deaths did not result in any significant public or other reaction against the hospital or the Pediatric Cardiac Surgery Program, even though two of the deaths had been clearly preventable.

In the overall scheme of things, the victims of these tragic events were from families of the least powerful in society. None of the families of the children who had died to this point were in a position to be able to influence large institutions, such as the HSC. Charlotte Caribou and Emalee Ulimaumi were from the far north, and the Goyals left the city shortly after the death of their son for an extended stay in India.

There is nothing to suggest that there was any discrimination at work with respect to these cases. However, it seems clear that if any of the deaths had involved a family that had more socio-economic standing, as Hinam suggested, events might have proceeded differently. As later evidence indicates, there were two cases in which people who were personally acquainted with individuals involved in the Winnipeg program were warned to take their children elsewhere for pediatric cardiac surgery.

Hinam's recommendation was also shaped by the earlier experiences of cardiac nurses in Toronto. Their subordinate status was underlined in 1981 when Susan Nelles, a nurse at Toronto's Hospital for Sick Children, was arrested for the murder of four children. Before Nelles's arrest, the nurses in the cardiology ward had raised concerns with their supervisors that low numbers of staff were endangering children's lives. They pointed to the deaths of 32 children in the ward. The charges against Nelles were eventually dropped for lack of evidence and motive. A Royal Commission, headed by Mr. Justice Samuel Grange, investigated both the deaths and the case against Nelles.

It is beyond the scope of this Inquest to review or comment on the Grange Commission. However, it is apparent that its impact on the nursing profession was significant. The Inquiry concluded that the deaths were the result of foul play and that the perpetrator was likely to be a nurse. Medical historian Katheryn MacPherson gives this description of how many in the nursing profession viewed the Inquest.

> Still convinced that foul play had occurred, inquiry attorneys aggressively interrogated the testifying nurses. Any expertise nurses might have offered to unravel the mysterious deaths was not sought out, while medical testimony was actively recruited and respectfully received. (MacPherson, page 256)

For many nurses the Inquiry confirmed that, while they had the responsibilities of professionals, they were still subordinate—lacking in control and authority. In telling the nurses to keep notes, Hinam was recommending that the Winnipeg nurses protect themselves from being made scapegoats.

Boyle testified that throughout April she had a number of conversations and meetings with nurses about the program. She recalled that Borton and Hinam came to speak to her following Vinay Goyal's death. She said they outlined their concerns with bleeding, cannulation, and team communication.

In early May, the Critical Incident Response Team held a meeting with the nurses. McGilton testified that at this meeting the nurses were encouraged to discuss their feelings about the deaths. She said there was also discussion of the fact that Odim did not appear to be distressed by the mortality rate. However, there was no discussion of surgical issues. McGilton told the Inquest:

> It was difficult for me because I'm not a sharing person with people I don't know that well anyway. I guess it was helpful to talk about it, but I came away from that thinking it hasn't fixed anything, you know, nothing is —nothing has changed, but I think that [Karin] thought it was important that we do go through that and talk about it, because it was such a very difficult time for us then. (Evidence, page 10,534)

Hinam testified that the meeting helped, in that each nurse no longer felt that she was the only one who was experiencing concerns about the program. She also indicated that at that point, the nurses thought it would have been appropriate if the program had slowed down, and complex cases had been sent out of province.

Youngson said that she made notes at home on her personal computer. When the HSC commissioned an outside review of the program in early 1995, she revised those notes to form a document to use in addressing that review. The file itself was deleted from her computer, but not until after the documents were printed. McGilton also began to keep notes on cases.

Boyle also spoke with Feser to determine if problems were arising in the PICU. She said that Feser informed her of the concerns that the PICU nurses had with the program.

PERFUSIONISTS

Throughout this period Maas spoke with the nurses and anaesthetists about their concerns. He said that after the Ulimaumi case, Swartz, McNeill, Youngson and Hinam were quite critical of Odim. In particular, they were concerned about cannulation and blood loss. Maas said the perfusionists sought to remain neutral, saying that "it takes time to learn someone's techniques, someone's abilities, and I don't believe that it's fair in one or two cases, particularly ones where some of these cases were as difficult as they were, to judge them. At least I am not capable to do that." (Evidence, page 6,983) Maas also said that after a number of the early cases, Youngson asked him to stand at the head of the table and observe Odim's cannulation style. Maas said:

> There seemed to have been more blood loss than we would have anticipated during cannulation, and that indicated that they were losing obviously blood during the venous cannulation in particular; and we were told by the nursing staff that he quite often cut some sutures, which were replaced and retightened. (Evidence, page 6,727)

APPROACHES TO WISEMAN

In the spring of 1994 several individuals approached Dr. Nathan Wiseman with their concerns about the Pediatric Cardiac Surgery Program. Wiseman was the head of the Division of Pediatric Surgery at the HSC. In that position he reported to both Blanchard and Bishop. When asked if his responsibility to each head was equal, he testified that it was "Difficult to say." (Evidence, page 39,370) In his testimony, Dr. Brian Postl, who was the head of pediatrics and child health from September onward, said he thought that Wiseman had no reporting responsibilities to him.

Youngson spoke to Wiseman several times on an informal basis. She said she did this because he was the head of pediatric surgery and was both approachable and respected. She testified that she indicated that she was very worried about what was going on in the program. When Wiseman indicated that he had spoken to

Hancock and been given a very positive description of what was happening in the program, Youngson urged him to scrub in for a procedure. He declined to do this. Youngson testified that Wiseman later explained that he declined because he did not take orders from nurses. Wiseman testified that he believed that if he simply came in to observe one of Odim's operations, it would change the atmosphere in the operating room and not be particularly useful as a tool for determining if anything untoward was going on. That view does not explain, however, why he did not take the concerns of the nurses more seriously.

Wiseman testified that while he did not supervise Odim's operations as a result of Youngson's request, he did assist Odim in an operation on April 15. He said at that time he had been made aware of the concerns over cannulation and observed Odim's progress. He said that he found it to be smooth and reminiscent of the work of Dr. Aldo Castaneda, the Boston surgeon with whom both Odim and Wiseman had once trained. After the operation, Youngson asked Wiseman about his assessment of Odim's cannulation. She testified that Wiseman described Odim's technique as cavalier. When asked about this description, Wiseman said:

> Well, we better look it up in the dictionary, I may have misused that word. Cavalier, to me, is bold. Aldo's technique of cannulating was bold. The Boston technique of cannulating is bold. Bold is different from timid. Bold isn't bad, bold isn't good, bold isn't timid, bold is different.
>
> Bold, in this case, means to cannulate without the presence of a clamp on the vessel. That's the Boston technique. It is just the technique, cavalier. (Evidence, page 39,540)

Dixon also spoke to Wiseman on a number of occasions. At one point she met with him informally at the scrub sinks and asked him if he would scrub in for an operation with Odim. She testified that he declined to do this, saying that Hancock was present to assist Odim. Dixon testified that she approached Wiseman because she thought Odim reported to Wiseman.

Hinam also testified that she spoke to Wiseman about her concerns and asked him to observe one of Odim's operations. She testified that he declined to do this. Wiseman testified that he could not recall this conversation.

After Borton spoke to Boyle about her concerns with the Goyal case, Boyle also made an appointment to speak with Wiseman about concerns that Hinam, Borton and Youngson had raised. She said that she went to Wiseman because Wiseman was in charge of pediatric surgery. Wiseman could not recall the specific meeting with Boyle, but agreed that it had probably taken place.

McNeill testified that she also had several discussions with Wiseman about the Pediatric Cardiac Surgery Program. She said these were informal discussions, often in the hallways, that in many ways constituted venting on her part. At the same time, McNeill hoped that Wiseman would become involved in the program in some manner.

> Well, I think in some ways, he was another surgeon, I knew he had had experience with cardiac surgery during his own training, and he did do ductus ligations and he does do a lot of intrathoracic work. So he has ability to, you know, he has some familiarity with what we were doing I guess.
>
> Again, at that point I get back to what I was saying before, about being really in some ways unsure whether these were valid concerns. And so he was somebody I saw who might be able to sort of reassure me, if you will, or perhaps agree that we should be looking at things more closely.
>
> Oftentimes our operating rooms or the operating setup is very small, like there is only five rooms that run, and it's not uncommon for surgeons to go in each other's rooms and stop in for a chat or things like that, and for an anaesthetist to go back and forth and that sort of thing.

> I thought that atmosphere of people, you know, the sort of going back and forth at times, and the fact that he was this titular head of pediatric surgery, I guess in the back of my mind—I shouldn't say I guess—in the back of my mind I was hoping perhaps he might help to come in, into the room and see how things were going, to see whether some of the interaction and/or procedure was going. (Evidence, pages 13,224–13,225)

Swartz also spoke, informally, with Wiseman about her concerns with Odim. Specifically, she recounted what, in her view, had happened in the Ulimaumi case. She stated she spoke to Wiseman because he was both a respected colleague and the head of pediatric surgery. She said Wiseman told her that he had been speaking to Hancock, who provided him with a very different account of the operation.

Wiseman testified that he never thought that he was being approached as Odim's supervisor, a position that he did not believe he occupied. From the evidence it appears that Wiseman was correct, he was not Odim's supervisor and Odim did not report to him. However, it should be noted that Wiseman had a responsibility as the head of pediatric surgery to ensure that the quality of surgery offered at Children's Hospital was of the highest degree. He was also a member of the panel of three pediatric surgeons charged with investigating pediatric surgical deaths, a member of the Children's Hospital Standards Committee and a member of the College of Physicians and Surgeons of Manitoba's Paediatric Death Review Committee. He was more than a disinterested colleague.

Swartz testified that, aside from her concerns about specific operations such as the Ulimaumi case, she was starting to have concerns about case selection. She realized that Giddins was under tremendous strain.

> And I found him tired, testy at times, and sometimes just run off his feet.
>
> And then you begin to wonder, is this guy making—where does he come from when he is making his decisions? Is he able actually to have time to sit down and think and make decisions? Is he able to also be, say the administrator of Variety Heart Centre and deal with all of those issues also? So—and I don't know who—see this, he didn't ever confide in me, for example, but I had to wonder how he was managing to do all of this. (Evidence, pages 15,731–15,732)

Swartz said that by the time Vinay Goyal underwent surgery, she was becoming concerned that the program had been restarted without sufficient preparation. She said that she had discussed her concerns with other anaesthetists.

> We had experience with these types of surgeries as anaesthetists, perfusionists and nurses. And I guess we assumed that Dr. Odim had experienced these procedures himself. Although I was—I had reservations, we went ahead with the procedure thinking that it wasn't—I mean, it is complex but it wasn't that complex. (Evidence, pages 15,390–15,391)

McNeill said that by the time of Vinay Goyal's death there were informal discussions among various HSC staff in which people asked why the program had not confined itself to low-risk cases. However there were no formal objections. She believed that everyone was still committed to the program.

ANAESTHETIC MEETINGS

McNeill testified that, from the middle of April onwards, she spoke informally to Ullyot about her concerns with pediatric cardiac surgery. She also said she had a formal meeting with Ullyot, in which she asked

Ullyot how she should go about raising these concerns. Swartz also raised her concerns with Ullyot, who recommended that Swartz meet with the head of the Department of Anaesthesia, Dr. Doug Craig.

Ullyot had a number of conversations with Swartz about her concerns with poor outcomes in the Pediatric Cardiac Surgery Program. The issue was also discussed at a pediatric anaesthesia meeting on April 18. Ullyot said that throughout late April and early May, she had a number of discussions with McNeill and Swartz about the cardiac surgical program.

In late April, shortly after McNeill's meeting with Ullyot, both McNeill and Swartz met with Craig. At that meeting they expressed their concerns over the program's mortality rate, particularly among the younger patients. McNeill testified that she and Swartz also had concerns that "we didn't know there was anybody actually monitoring the outcomes of the program." (Evidence, page 13,228)

> On a more personal level, we asked him at that time what our responsibility was, as department members, to give anaesthetics for surgery if we felt that we couldn't do it or were not willing to do it, or had, you know, had any significant reason for not wanting to participate.
>
> We asked him that and he reassured us that, you know, if we had valid and significant reasons for not wishing to participate in a surgical procedure of any kind, at any time, we could refuse to do so.
>
> I guess the exception being obvious, if you are the only person available and the patient needed—you know, I am talking in general circumstances. (Evidence, page 13,229)

Swartz testified that it appeared as if there was no one in charge of the program.

> There had been really no accountability that we could tell. There had really been no reviews or assessments of morbidity and mortality. We didn't know what was—you know, what was the controls of the program. (Evidence, page 15,748)

McNeill testified that at the meeting with Craig, she and Swartz also asked if there was any mechanism by which he could help them instigate a review of the program. She said that at the time Craig was supportive of the pediatric cardiac anaesthetists and was aware of the steps they were taking.

In his testimony, Craig indicated that Swartz and McNeill had told him they were worried about the results from pediatric cardiac surgery, that they had not been able to get anyone to listen to their concerns and that they wanted to know what action they might take. Craig said he told them that no anaesthetist was obliged to provide a service if the anaesthetist felt the situation was unethical or medically inappropriate. In testimony he pointed out that at the HSC, anaesthetists were allowed to refuse to provide anaesthetic care to patients undergoing abortions or for certain operations on patients who refused to receive blood products. He also said the HSC had respected the wishes of anaesthetists who "don't want to or can't work with an individual surgeon." (Evidence, page 34,480)

Craig testified that he believed from his conversations with McNeill and Swartz, and from previous conversations with Ullyot, that these concerns had been effectively communicated to Wiseman. He also testified that he had assumed that these concerns had been communicated to Odim. He was correct on the first point, but incorrect on the second point. It would appear that Swartz and McNeill had both been left very frustrated by their conversations with Odim following Vinay Goyal's death and saw little point in raising concerns with him.

Craig then spoke with Ullyot, and it was agreed that Craig would contact Blanchard, while Ullyot would contact Wiseman. Following that meeting, Craig spoke with Blanchard and told him of the concerns that his department members had with the Pediatric Cardiac Surgery Program. Blanchard testified that this was the first time he had heard of concerns with the program (Evidence, page 36,498). He asked Craig to keep him informed of further developments, but testified that he could not recall taking any other steps.

APRIL 18 – MEETING OF THE SECTION OF PEDIATRIC ANAESTHESIA

On the same day as Vinay Goyal's second operation, the regular monthly meeting of the Section of Pediatric Anaesthesia was held. McNeill and Swartz were in the operating room, looking after Vinay Goyal until well after 1900 hours, when the meeting apparently ended. Of the four anaesthetists who provided anaesthetic care for pediatric cardiac patients, Reimer was present at the meeting. At this meeting he discussed the concerns that the four anaesthetists had with cannulation problems and lengthy surgical times.

The members of the section resolved to appoint a liaison between Anaesthesia and Surgery. The liaison person's function was to communicate the concerns of the anaesthetists to those in charge of the program and those responsible for monitoring the surgeon, on whom most of the concerns centred. The role of the liaison also apparently was to continue over the longer term and was not intended to simply be a one-shot effort. The four anaesthetists involved in the pediatric cardiac program were to meet in order to select the person who would act as the liaison.

THE CASE OF DANIEL TERZISKI

ISSUES

Daniel Terziski died on April 20, 1994, following a high-risk Norwood operation. His case gives rise to the following issues:

- Should Daniel's condition have been diagnosed earlier?
- Was Daniel's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Daniel healthy enough to undergo an operation?
- Should the HSC team have attempted the operation or should Daniel have been referred out of province?
- Should there have been better planning for this procedure?
- Did the length of surgery contribute to Daniel's death?
- Was there appropriate post-operative care?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Daniel Terziski, the third son of Kiril and Danica Terziski, was born on March 18, 1994, at the Misericordia General Hospital. An ultrasound done at six months gestation was reported as showing a normal fetus. At birth, Daniel was considered an active and healthy baby and was discharged with his mother on March 23. It is clear now that he was in fact suffering from a very serious heart condition at the time of his discharge.

One of the first questions raised in this case is the accuracy of the ultrasound done at six months gestation. In their joint report to this Inquest, Duncan and Cornel state:

> The information contained in the medical record suggests that a fetal echo was done and reported as normal. This seems unlikely given the fact that there was only one atrio-ventricular valve. (Exhibit 354, page 6)

As Dr. Walter Duncan testified, Daniel did not have a tricuspid valve—therefore the scan could not have shown a healthy heart.

Cornel also noted that if the perinatal and neonatal diagnoses had identified the defects earlier, the treatment might have been more successful. Cornel testified:

> When dealing with univentricular circulation, one of the things that we like to avoid as early in life as possible is massive volume overload of the ventricle. That means we like to try and control the amount of blood flow through the lungs so that the return to the ventricle is less than it might be, so that there is much less work for the heart to do. And earlier diagnosis and more precise management can reduce those problems, and sometimes earlier surgery is an advantage. (Evidence, page 44,790)

Very soon after going home, Daniel's mother noted that Daniel was weak, tired easily and had difficulty feeding. On at least two occasions his mother took him to a nursing clinic at the HSC Women's Pavilion. She testified that she also took Daniel to see the family doctor, Dr. Hugh Taylor, who encouraged her to supplement his feedings.

THE DECISION TO OPERATE

On April 13, when Daniel was 26 days old, his mother took him to see Taylor's partner, a Dr. Friesen. The doctor quickly determined that Daniel needed more significant attention and told Danica Terziski to take her son straight to the Children's Hospital emergency department. At the HSC, he was seen by Giddins, who told Danica that her son had a serious heart defect and needed surgery.

Daniel was admitted to neonatal intensive care (NICU) at 1620 hours on April 13. The admitting NICU resident examined Daniel and found he was breathing rapidly, at 80 breaths a minute at rest, with moderate in-drawing below the ribs and the breastbone, and nasal flaring. Daniel was pale, his liver was enlarged and he had poor circulation to his lower body. His oxygen saturation was low, and a heart murmur was detected. A chest X-ray showed a small right ventricle, a large left heart and evidence of pulmonary edema. An echocardiogram showed:

- tricuspid atresia (he had no tricuspid valve)

- transposition of the great arteries (his arteries did not connect to the appropriate ventricles)
- a small ventricular septal defect (there was a hole in the septum between the ventricles)
- a patent foramen ovale with an unobstructed right-to-left shunt (the foramen ovale was open)
- a rudimentary right ventricle (his right ventricle was underdeveloped)
- aortic coarctation with a hypoplastic aortic arch (his aortic arch was pinched and underdeveloped).

The transposition of the great arteries and the underdevelopment of his right ventricle meant Daniel had functional hypoplastic left heart syndrome. Cornel said this could in some measure account for the delay in making a proper diagnosis. Giddins and Odim concluded that Daniel needed a stage one Norwood repair, as described in Chapter Two of this report.

The cardiology resident, Doyle, also examined Daniel before he was transferred to the NICU. She wrote that he needed open-heart surgery in the next 24–48 hours and might require transfer to another centre (Exhibit 12, page TER 45).

In his initial report, Cornel wrote:

> The diagnosis appears straightforward so far as it goes, however the aortic valve and ascending aorta are described as mildly hypoplastic the ductus appears to have shunted very little on echo leading me to the conclusion the aortic outflow was supporting the systemic circulation. The VSD is described as small but no measurements are given and arm pulses were normal and blood pressure was normal or elevated.
>
> I suspect the decision to perform a Norwood type operation was probably correct but the data that I have on hand could also support repair of coarctation with distal arch augmentation and pulmonary artery banding as the primary procedure. (Exhibit 353, page 30)

However, in his later testimony, Cornel stated that having reviewed additional evidence, including the transcripts of some of the witnesses, he believed a Norwood was required. In his assessment, Dr. Walter Duncan wrote:

> Would question wisdom of Norwood attempt this early in surgical experience, but again, the child was unstable and might not have tolerated transfer. Canadian results with Norwoods are generally poor in any event. (Exhibit 20, document 363, page 5)

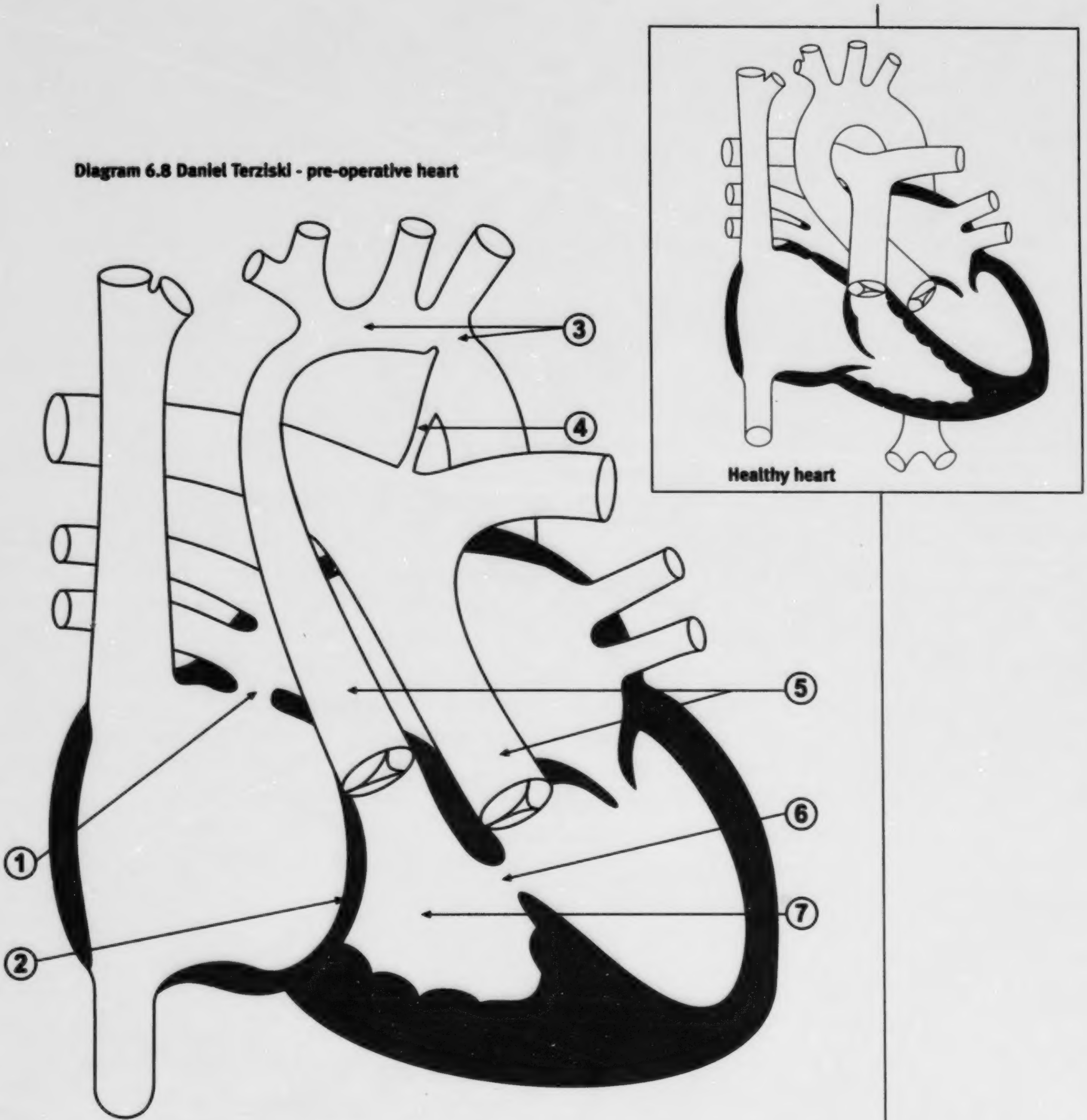
In his testimony, Cornel said that the decision to undertake a Norwood in Winnipeg at this point was very questionable, particularly considering the outcomes in the Caribou, Ulimaumi and Goyal cases.

> I would expect that after these three deaths that the morale of the group is not good. If there was this failure of communication that took place in the case of Vinay Goyal, I have to wonder how functional the team was. To undertake really one of the most difficult procedures in [the] book under those conditions is unwise. The outcome is likely to be bad, and all that can do is add to the troubles for the team. (Evidence, pages 44,772–44,773)

CONSENT

On April 14, the cardiology resident, Doyle, on behalf of Giddins, noted in the chart that Giddins had "discussed with the parents the need for surgery. Dr. Odim to give impression regards surgery here or elsewhere." (Exhibit 12, page TER 25)

Diagram 6.8 Daniel Terziski - pre-operative heart



1 – Patent foramen ovale
2 – Tricuspid atresia
3 – Aortic coarctation with hypoplastic aortic arch
4 – Patent ductus arteriosius
5 – Transposition of the great arteries
6 – Ventricular septal defect
7 – Rudimentary right ventricle

Odim and Hawkins met with Danica and Kiril Terziski that afternoon. They explained Daniel's heart defect. His mother was concerned about his prognosis and life expectancy and asked about post-operative complications. Hawkins indicated that she asked very pointed but appropriate questions. No final decision was reached at this meeting.

In her testimony, Danica Terziski indicated that she had asked about a transplant for her son, but had been told that a transplant was not practical in Daniel's case because of problems with rejection. She was also given a description of the defect that her son had. She testified that she was told that a reconstruction of his heart by way of a Norwood had a fifty-fifty chance of success. Odim and Hawkins also discussed comfort care with her.

The Terziskis were told it might be possible to have the operation done outside Winnipeg, in a centre such as Boston or Toronto. When Danica Terziski asked Odim where he would want a child of his operated on, she testified that he responded that it was not his place to comment on such a decision. She testified that Giddins indicated that the team in Winnipeg was as capable as any team elsewhere.

The Terziskis subsequently suggested that Dr. Christo Tchervenkov, a surgeon under whom Odim had trained in Montreal, come to Winnipeg to perform the operation. The idea had particular appeal to the Terziskis, since both Kiril Terziski and Tchervenkov were of Bulgarian descent.

Danica Terziski raised the idea with Hawkins, who according to Danica's testimony, said that it would not be possible for Tchervenkov to operate in Manitoba because his insurance would not cover the procedure. In her testimony, Hawkins said that she could not recall saying it would be impossible to have Tchervenkov perform the operation. However, she did recall saying that it would be difficult. Despite this, the Terziskis also raised the idea with Odim and Giddins. Danica Terziski testified that Giddins became very defensive at that point. She said no one suggested that they go to Tchervenkov in Montreal. Instead they were told that the Winnipeg team was capable of performing the operation. The Terziskis eventually consented to surgery in Winnipeg.

In his testimony Giddins said that he could only vaguely recall the conversation regarding Tchervenkov. He denied that he had been either impatient or angry with the Terziskis. He also testified that "intra-provincial licencing requirements, liability matters, scheduling of various individuals in various places" were, among other issues, matters that may have stood in the way of Tchervenkov operating in Winnipeg (Evidence, page 3,735). It would appear from the testimony that no efforts were made either to contact Tchervenkov or to discover whether or not these impediments would have actually prevented him from coming to Winnipeg to perform the operation.

In the death summary, Odim wrote, "All the management options were presented to the family including palliative medical therapy, heart transplantation, and the Norwood staged operative repair. The family was well informed about the natural history of each option and the risks and eventually decided upon the Norwood approach." (Exhibit 12, page TER 10) There was no mention that the family was actively seeking to have Tchervenkov come to Winnipeg to do the operation or that they were considering having the operation performed elsewhere, both of which the family considered, but from which they were dissuaded.

PRE-OPERATIVE STATUS

Daniel remained in the HSC from April 13 until his death on April 20, following his operation earlier that day. Daniel's health deteriorated throughout his stay in hospital. During the final two-and-a-half days preceding surgery, there was rapid deterioration.

On Thursday, April 14, Doyle wrote in the chart that Daniel remained stable overnight, with a heart rate of 160 beats per minute. However, he did require a dose of Lasix, for increased respiratory distress.

On April 15 Doyle described Daniel as being unchanged in his condition. He required intermittent doses of a diuretic for treatment of pulmonary edema related to high pulmonary blood flow. He also had a decrease in the strength of his pulses in his legs, which indicated a reduction in blood flow to his legs (Exhibit 12, page TER 27).

On April 16 Giddins noted that Daniel still appeared unchanged, although he was developing a difference in blood pressures above and below the aortic coarctation. Giddins also indicated that the parents had agreed to a plan for surgery on Tuesday or Wednesday. They were to come in for formal consent discussions on Monday, April 18. In her testimony, Danica Terziski indicated that she recalled that the operation had been originally scheduled for Monday, April 18 but was rescheduled to accommodate Vinay Goyal's surgery.

On Sunday, April 17, Daniel's condition deteriorated significantly. He struggled to breathe, with a respiratory rate of 80 to 90 breaths a minute. Each time he breathed he had subcostal in-drawing. He grunted with activity and was pale and jaundiced. He was also blue around his mouth, a further sign of deterioration. When his regular dose of diuretic did not relieve his rapid breathing, another dose was immediately given. At 0900 hours his blood pressure had dropped, but by mid-afternoon it had returned to normal.

Daniel's condition continued to deteriorate. The doctors could no longer feel a pulse in Daniel's femoral artery (in his groin), indicating that the circulation to his legs was worsening. A chest X-ray done at 0520 hours showed acute pulmonary edema. Subsequent X-rays done throughout the day showed signs that the lungs were becoming more dense, particularly in the left lower lobe, and losing lung capacity. After discussion with Giddins, Dr. Jacques Belik, one of the neonatologists, decided that Daniel should be artificially ventilated, in an attempt to decrease the workload of Daniel's heart. Daniel was therefore sedated and given a drug to relax his muscles, so that a breathing tube could be placed into his windpipe. The tube was then attached to a ventilator that took over Daniel's breathing.

During the course of the day, Daniel regurgitated some stomach contents. In his report, Cornel speculated that some of this liquid might have entered his lungs (a process known as aspiration). If Daniel had aspirated, this could have led to an infection in the lungs.

Later that evening, Daniel's condition was clearly unstable. His oxygen saturation was rapidly declining. As a result, the doctors decided that he required manual ventilation with 100 per cent oxygen. In manual or hand ventilation, the patient is disconnected from the ventilator. Using one hand, a doctor, nurse or respiratory technologist squeezes a bag connected to the breathing tube, thus controlling the rate of breathing and the size of each breath delivered. (This technique sometimes, but not always, offers better control of the delivery of oxygen than does mechanical ventilation, using a ventilator.) Daniel was also treated with Lasix (for worsening pulmonary edema) and dopamine (to strengthen the function of his heart).

Overnight, Daniel's condition was very unstable, with his heart rate dropping severely several times. Because his oxygen saturation was so low, hand ventilation was continued.

At 0800 hours April 18, Odim wrote in Daniel's chart: "Patient has shown signs of destabilization from single ventricle lesion with torrential pulmonary flow and obstructed systemic output via VSD." Daniel had congestive heart failure that required that he be intubated. In addition, he had a low urine output. According to Odim's note these factors had "increased his surgical risk appreciably." (Exhibit 12, page TER 37) He was scheduled for surgery on Wednesday, April 20.

At 2230 hours, Daniel's oxygen saturation fell dramatically and, despite manual ventilation, he continued to deteriorate. Air entry to his lungs was obviously greatly decreased and the amount of carbon dioxide in his blood was more than twice the normal. According to Cornel, this was a sign that Daniel was close to asphyxiating. His endotracheal tube had to be changed because it was blocked with yellow secretions. In his report Cornel referred to these secretions as a purulent mucus plug. In testimony he described such a plug as:

> A very hard, thick collection of secretions that build up on an endotracheal tube, and it can—we try to keep them removed by suctioning but they don't always get removed. It's more likely to happen when there is ongoing infection. (Evidence, pages 44,797–44,798)

As a result of the presence of these secretions and a chest X-ray that showed increased areas of density in the right upper lobe, Cornel testified that:

> I would have wanted the baby placed on antibiotics, cultures taken, and a period of ventilation, with controlled ventilation, and to try and reduce the pulmonary blood flow prior to surgery and get the baby as completely stable as possible. (Evidence, page 44,798)

Cornel, in his written report, concluded that

> the infant was not in the most satisfactory possible condition for surgery. I believe a further delay of perhaps 24 hours to allow recovery from the severe hypoxic episode [the rapid decrease of oxygen in the blood] and to treat the possible respiratory infection would have been of benefit. (Exhibit 353, page 31)

This is one more case in which the consulting witnesses who appeared before this Inquest have raised the question as to whether or not a patient was taken to surgery with an infection.

PREPARING THE NICU STAFF

Daniel was one of the first neonates upon whom Odim operated in Winnipeg and was the first to die. Debra Armitage, the senior nurse in the NICU, said that she recalled a pre-operative meeting for this operation quite vividly. She recalled that Belik asked Odim detailed questions about post-operative care.

> And the answers that he was—these were very specific questions from Dr. Belik—the answers that we were getting from Dr. Odim were less specific, they were actually quite vague. In actuality, they were to the point that he was answering the usual, or what you are used to, or not being really specific. Our previous experience had been that we were very much aware which inotropes we used, how much we needed to use of them and specifics like that.
>
> We then moved on to ventilatory support of the child post-operative, and again Dr. Belik was asking very specific questions about how Dr. Odim liked his post-operative management in terms of ventilation, and again was asking very specific questions about the degree of pressures that the ventilator

> delivers, and the rate of the ventilator, and whether or not—where he liked to keep the pH of the blood at in terms of what it was that we were trying to accomplish. Again, the answers were vague, with him repeating, the usual, or whatever you are used to.
>
> And I was somewhat disconcerted at that point, because I certainly expected much more from him. I felt like I was essentially standing there with a light bulb on over top of my head, because I was struck with this amazing sense that he didn't know what he needed or wanted post-operative. (Evidence, pages 29,430–29,431)

Armitage said that, in the past in situations like this one, the surgeon would set very clear parameters as how to monitor and assess the patient in the NICU. The evidence suggests that Odim failed to assist the NICU in planning for Daniel's care. That failure seems to have stemmed from his inability to communicate what he wanted them to do and what they ought to do.

THE OPERATION—APRIL 20

On the morning of Wednesday April 20, Daniel underwent a Norwood Stage I palliation operation. To deal with the transposition of the great arteries and the underdeveloped right ventricle, the pulmonary artery and the aorta were connected to create a common vessel. (This is referred to as the division and anastomosis of the pulmonary artery to the ascending aorta.) The point where the left and right pulmonary arteries formerly connected to the trunk of the pulmonary artery was closed. A homograft was to be used to augment the ascending aorta. This operation also involved an atrial septectomy, division of the patent ductus arteriosus and the placement of a four-millimetre right-modified Blalock-Taussig shunt. The operating team is set out in the accompanying chart.

TABLE 6.9: Persons involved in the operation on Daniel Terziski, April 20, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistants	B.J. Hancock, V. Hota (resident)
Anaesthetist	H. Reimer
Scrub nurses	S. Scott, C. McGilton
Circulating nurses	B. Zulak, W. Yakinchuk, C. Youngson
Perfusionists	T. Koga, M. Maas

The operation that Daniel was to undergo was a high-risk procedure. While the length of surgical time is always an important factor in pediatric cardiac surgery, it is of particular importance in a Norwood. Because Daniel had only a single working ventricle, that chamber was required to work twice as hard as normal. A lengthy operation could compromise this ventricle's function and increase Daniel's risk of serious complications. (Long bypass times could injure his lungs and could compromise his health, since during the post-operative period it might have become necessary to adjust his pulmonary blood flow. This is best done with healthy lungs.)

Because of all the risks involved in a Norwood operation, it was important that the operating team be well prepared. In this case, Odim did not consult in advance with either Reimer or Kesselman, both of whom had experience with Norwoods. Nor did he speak with any of his previous teachers.

Deep hypothermia with circulatory arrest and cold-blood cardioplegia were used for myocardial protection.

TABLE 6.10: Length of phases of the operation on Daniel Terziski, April 20, 1994

Phase of the operation	*Time taken*
Induction	1 hour
Bypass	5 hours 59 minutes
Aortic cross-clamp	1 hour 42 minutes
Total surgical time	8 hours 40 minutes
Total operating-room time	10 hours 1 minute

UNTOWARD EVENTS DURING SURGERY

Preparation of the homograft

McGilton testified to one complication during Daniel's surgery.

> I remember we used homograft for Daniel and I remember telling Dr. Odim several times during the case to give us lots of warning because there is a certain protocol that you have to follow for thawing it out. It's kept on dry ice and it's protocol that you follow, circulating nurse will get it, thaw it in the sterile package then it will be put on the scrub nurses' table and kept in saline for I think it's ten minutes. It's very, very carefully timed. It's very, very important. It's a very, very important—I don't want to say piece of equipment, it's part of a child, that you can't waste it, you know, you want to do it right. And I remember telling him several times please tell us when you think you're going to need it ... (Evidence, page 10,519)

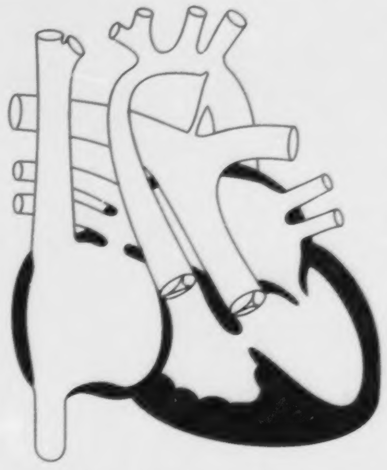
McGilton testified that she reminded Odim of the need to give her sufficient notice several times during the course of the operation. Despite this, she said, she did not receive adequate notice.

> It got to the point where, okay, we need it, we need it now, where is it and, you know, it was a big panic and a big rush to get it and he wanted it and I didn't want to give it to him and it was—oops, so he ended up I think putting it in maybe a minute or two ahead of when he should have. (Evidence, page 10,520)

Odim acknowledged that, as he recalled the event, he had not given enough notice, but felt he had waited the appropriate period of time before applying the homograft.

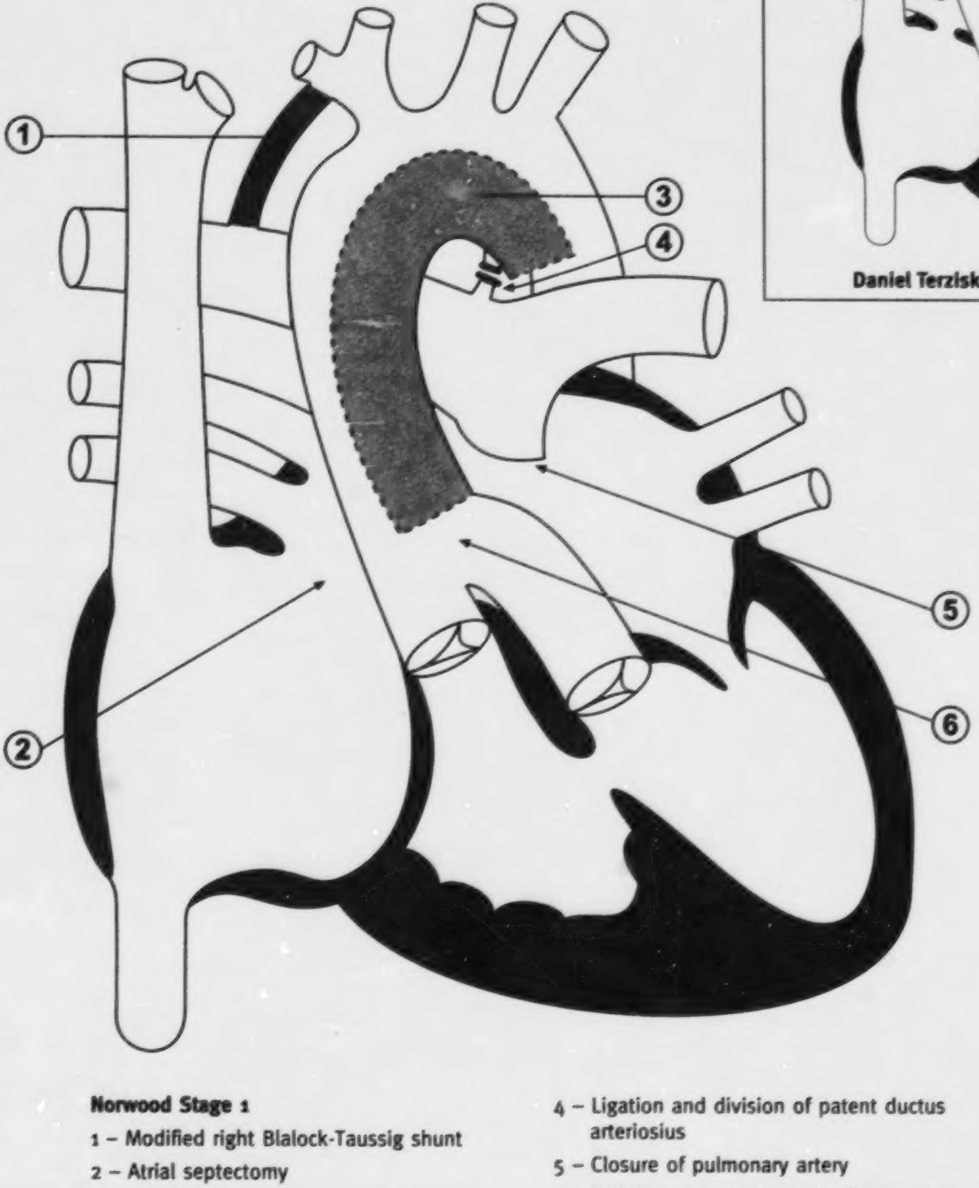
Removing the cap from the line

At another point in the operation, Odim wanted to check a pressure by connecting the aortic cannula to a transducer. Normally the surgeon does this by either removing a cap on or a connector in the line and then connecting the cannula to a line to the transducer. To ensure that there is no blood loss, the cannula is clamped for a brief period of time while the surgeon removes the cap from the line. Youngson and McGilton



Daniel Terziski – pre-operative heart

Diagram 6.9 Daniel Terziski – post-operative heart



Norwood Stage 1

1 – Modified right Blalock-Taussig shunt

2 – Atrial septectomy

3 – Homograft augmentation of ascending aorta and aortic arch

4 – Ligation and division of patent ductus arteriosius

5 – Closure of pulmonary artery

6 – Division and anastomosis of pulmonary artery to ascending aorta

testified that Odim struggled to remove the cap. Youngson testified that after a time Maas indicated that they had to unclamp the line to allow blood to flow to the patient. The clamps were removed and then, unexpectedly, Odim took the cap off. Youngson gave the following description of events.

> It finally comes right off in his hand, and now we have got blood shooting out of this cannula, because this is where the blood is coming back from the pump under, not a lot of pressure, but there is some pressure behind this flow of blood, and potentially air going into the aortic cannula. And I remember it was just a mad scramble to get this thing back on, stop the pump again, just make sure there is no air, for just a second or two, and then carry on. It was just a very startling incident. (Evidence, page 8,435)

It does not appear that the event caused any medical issues for the patient.

Problems with the shunt

While Daniel was being rewarmed, Odim constructed a 3.5 millimetre Blalock-Taussig shunt. The purpose of this shunt was to allow blood to flow from the ventricle to the lungs. The shunt was connected to the aorta (which had been reconstructed) and the pulmonary artery. After placement of this shunt, Daniel was taken off bypass. His oxygen saturation was found to be low (60 per cent as opposed to an anticipated 80 per cent). This was a sign that the shunt was not allowing enough blood to flow through. As a result, Daniel was put back on bypass. Odim then adjusted the shunt. Daniel was taken off bypass and Odim discovered that the shunt was still not permitting sufficient blood flow. As a result, Daniel was placed on bypass a third time, at which point a new four-millimetre Gortex shunt was put in place. Odim's operative report describes only one of these two revisions. These events added considerably to the length of time Daniel spent on bypass.

Odim also delayed closing Daniel's chest, choosing to use a silastic sheath. In his note, Odim wrote that Daniel's condition was stable on transfer to the NICU at 1901 hours. In testimony, Reimer agreed with this assessment, although he added that 'stable' was a generous term when one was speaking of a child who had undergone this particular operation.

THE ASSESSMENT OF THE CONSULTANTS

Cornel, in his written report, stated that the general plan for the operation was consistent with good practice. However, he identified a number of concerns with the actual procedure.

> The nasopharengeal [sic] temperature was as much as three degrees C above rectal during cardiopulmonary bypass. (Exhibit 353, page 31)

In testimony, Cornel explained that this may have been of limited significance. It is, however, an indication that that body was not cooled uniformly.

> The circulatory arrest time of one hour 42 minutes was very long and surprisingly so in view of what appears to have been satisfactory anatomy. (Exhibit 353, page 31)

In his testimony, Cornel said the favourable aspect of the anatomy he was referring to was the fact that the descending aorta was near-normal in size. This provided a relatively large vessel wall on which to sew the patch. In testimony, Cornel commented:

> In his operative report, Dr. Odim didn't mention any particular technical difficulties, so it's a little hard to figure out where the time went. (Evidence, page 44,810)
>
> The choice of a 3.5 mm graft for a Blalock shunt was unnecessary and more appropriate for a central shunt. Changing the shunt added almost 1 hour to what was already a very long cardiopulmonary bypass time (total five hours fifty-nine minutes). (Exhibit 353, page 31)

Cornel testified that he believed a larger graft would have been more appropriate and easier to attach. In his report to this Inquest, Hudson commented on the length of the operation.

> The duration of CPB was very long, in part because of the need to revise the Blalock-Taussig shunt twice before satisfactory pulmonary blood flow could be achieved... The long duration of CPB could have contributed to the eventual outcome. Also, the duration of TCA was much longer than is generally accepted at 18°C. If the patient had survived, he would have had an increased risk of major neurologic morbidity. (Exhibit 307, page 4.10)

In his testimony Odim said that the operation was longer than expected because Daniel's tissues were friable (tore easily). This required that he take extra care—and time—in his suturing.

POST-OPERATIVE COURSE

The post-operative care of a child who has undergone a Norwood operation can be as difficult as the procedure itself. It is extremely important that there be a proper balance between the blood flow to the child's body and to the lungs. In his testimony, Odim said that in a sense one takes the operating room to the intensive care unit to manage these babies.

When Daniel arrived in NICU, the attending neonatologist was not present, having been called to attend in another part of the hospital. Instead, a resident met Daniel and the team accompanying him from the OR. Reimer testified that after he explained the anaesthetic issues to the resident, the resident "immediately wandered off to look after another baby, who I thought at the time had a relatively trivial problem." (Evidence, page 18,876)

Reimer testified that he was dismayed by this and by the fact that Daniel was placed in the back corner of the nursery. Reimer testified:

> Traditionally, infants who are more critically ill are nursed closer to the desk. That's simply a reflection of that being a location where there are usually more people around, help is more readily available, and they can perhaps be watched a little bit more closely than they are elsewhere. (Evidence, page 18,875)

In her testimony, Dr. Molly Seshia, the head of the NICU, disputed Reimer's assertion that there were priority cubicles in the NICU. Seshia also said that as a result of the Terziski case, the NICU put into place a practice whereby, whenever a child is coming from the surgical ward, the attending neonatologist must be called back to the ward to be present. This also required some form of notice from the surgical unit that the child was about to be transferred.

In light of these events, Reimer said:

> I thought there was under appreciation by the staff, again, of the fragility of this child's condition, or of a child's condition who has had this procedure, and general under appreciation for, I guess, just the degree of illness they have and how easily they can decompensate. (Evidence, page 18,876)

The major issue that needed to be watched carefully in the post-operative management of Daniel's case was the balance between the blood flowing to Daniel's body, as opposed to that flowing to his lungs. His condition was such that a fatal imbalance could develop rapidly.

According to Odim, Daniel's condition was stable for 40 minutes after Daniel arrived in the NICU. At that time, he and Giddins went to see a patient in another unit. In his testimony, Odim said that he could not provide more information about this other patient. After ten minutes, Odim said, he then returned to Daniel's bedside. By that time, his oxygen saturation had dropped into the sixty per cent range and, despite hand ventilation, did not improve. Odim opened Daniel's chest at 2023 hours to check the status of the shunt. Odim testified that he asked the nurses to organize a sterile setup so that he could quickly provide some assistance to Daniel.

> There was a lot of scurrying around to get sterile drapes and towels so that I could proceed, and the Betadine to spread on the chest as an antibacterial. (Evidence, page 24,828)

Armitage testified that the scene was chaotic at this point.

> We were not prepared at any time to go back into Daniel's chest. In essence, we were caught off guard very badly by the fact that we were not prepared to go back into this chest. We needed equipment and supplies and personnel in order to do that, and we had none of that available. (Evidence, page 29,434)

Armitage said that it was necessary to essentially replicate the OR setting.

> And we have forceps, we have things like that available to us in NICU, but not the actual surgical instruments that are required in that circumstance. There are special kinds of sutures that we do not stock, simply because we do not use them. There are various other bits of supplies that are needed.
>
> There, again, our concern also was in talking about personnel is that neonatal nurses are highly specialized in what we do. That does not include being a scrub nurse. We are not familiar with the instruments. We don't know what their names are, never mind what they are used for. So, for him to ask me to hand him whatever, I simply wouldn't be able to do that.
>
> The other point that I want to make in terms of equipment or possible supplies, the OR is one floor down from us. While it might take you only 30 seconds to run there, they have a very big supply room and their supplies are somewhat overwhelming, and for me to run into that room to find out what it is I am looking for, even if I know what it looks like, there is a huge time lag and the baby may very well be dead by the time I find it.
>
> We were fortunate in fact that Carol Youngson was still in the OR cleaning up and so she was able to come up and assist. (Evidence, pages 29,435–29,436)

After opening the chest, Odim deemed the shunt to be viable. Daniel, however, continued to deteriorate. Odim gave this description of what happened next:

> ... the blood pressure continued to drop and we lost our sinus rhythm, and Daniel was in a cardiopulmonary arrest.
>
> I tried vigorously to resuscitate the heart with massage and drugs, but after a period of time of all these attempts, we were never able to get any action back, and Daniel expired. (Evidence, page 24,832)

Despite 40 minutes of open-heart massage and vigorous resuscitation, Daniel died at 2059 hours.

AUTOPSY

Daniel's death occurred within a short time of an operation and therefore, under the rules of the Office of the Chief Medical Examiner, should have been the subject of an autopsy. Despite this, no autopsy was performed. There is conflicting testimony as to how that happened.

Danica Terziski testified that, on the evening of Daniel's death, she was informed that autopsies were compulsory in cases such as Daniel's and that she could expect a report in a matter of weeks. This information was accurate. However, it was still necessary for someone to obtain her formal consent. This did not happen.

She testified that the following morning, Odim telephoned her. In the course of their conversation, Danica testified that Odim:

> ... asked if we could have another look around. He explained that this is a very rare, complex procedure and maybe we can learn something from it. (Evidence, page 1,774)

This left her with the impression that Odim wished to perform research on Daniel, in addition to the mandatory autopsy. She withheld her consent to what she thought would be research. In his testimony Odim said that he could not recall any of the specifics of this conversation. He did state that on the evening of Daniel's death, he believed that Belik had taken responsibility for arranging the autopsy. If he had thought so, it is unclear why he phoned Danica Terziski the next morning.

In his testimony, Dr. Peter Markesteyn, the Chief Medical Examiner, gave a slightly different account of the events, although his evidence is second-hand. Markesteyn testified:

> I was consulted by the medical examiner investigator, or the M.E.I., about the fact that an autopsy had been ordered, or Dr. Odim would get permission.
>
> *Q:* I see.
>
> *A:* He would get an autopsy, or Dr. Giddins or both and, unfortunately, that it not, due to misunderstandings, that did not happen.
>
> *Q:* So your information was that Daniel Terziski would have an autopsy?
>
> *A:* Yes.
>
> *Q:* Performed by the hospital?
>
> *A:* Yes. (Evidence, pages 38,676–38,677)

The written notes of the MEI indicate that in this case Odim informed the Chief Medical Examiner's office that he would contact the family and arrange for an autopsy.

The evidence tends to suggest that Odim did in fact telephone Danica Terziski the morning after her son's death to ask for consent to carry out an autopsy. It also suggests that he did not make his request very clear, and as a result of a misunderstanding, Danica told him she would not consent to what he was asking. She had already accepted the fact that an autopsy would be conducted. Odim, however, believed that she would not consent to the holding of an autopsy. Odim never forwarded this information to the CME's office. As a result, the CME was left with the impression that the HSC was arranging and carrying out an autopsy.

Since Markesteyn believed that the hospital pathologist was going to carry out an autopsy, and was never informed to the contrary, he did not order one on his own.

The matter was exacerbated when staff in the CME's office placed an official release on the chart, indicating that the CME was not going to direct that an autopsy be held. Markestyn said this was done because his office had been informed that the hospital would seek the family's consent to an autopsy. Obviously that release was premature until it was known that the consent had been obtained. This release, combined with a lack of a written consent on the chart, was apparently understood by hospital staff as an indication that an autopsy was not to be held at all. Therefore, the baby's body was soon released to the family for burial. The family assumed that the autopsy had been performed before the body had been released and proceeded with funeral plans for Daniel. It was not until several months later, when Daniel's mother inquired about the status of the autopsy report, that it was determined that an autopsy had in fact not been performed.

Unfortunately in this case, it appears from the evidence that cost factors may have played a role in the decision of the staff in the Chief Medical Examiner's office not to follow the usual procedure and order an autopsy. Markestyn testified that when the hospital asks for an autopsy report, the hospital must pay for the cost of performing the autopsy. When his office orders an autopsy, the cost of the autopsy is paid for from the Chief Medical Examiner's budget. In this case, the decision not to place a Chief Medical Examiner's direction on the chart seems to have stemmed from the desire on the part of the CME's office to avoid paying for the autopsy. These events give rise to recommendations in the final chapter of this report.

FINDINGS

Daniel Terziski was born with a very serious heart defect. That defect led to his death following an operation intended to be the first step in a long-term plan for amelioration of the defect. But the procedure was a high-risk one. Many children in Canada, with the same defect as Daniel had, died following surgery. The questions that arose from this case included the decision to perform the procedure here in Winnipeg, as well as the manner in which the case itself was handled.

The issues are:

- Should Daniel's condition have been diagnosed earlier?
- Was Daniel's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Daniel healthy enough to undergo an operation?
- Should the HSC team have attempted the operation or should Daniel have been referred out of province?
- Should there have been better planning for this procedure?
- Did the length of surgery contribute to Daniel's death?
- Was there appropriate post-operative care?
- What was the cause of death and was it preventable?

Should Daniel's condition have been diagnosed earlier?

- Finding

Two of the consulting witnesses who appeared before this Inquest indicated that Daniel's heart defects should have been identified before his birth. In addition, his mother sought medical attention several times before Daniel was properly diagnosed. While Dr. Walter Duncan indicated that the type of defect that Daniel suffered from is difficult to detect, early detection might well have led to more effective treatment of Daniel. The evidence suggests that Daniel's condition should have been detected earlier than it was.

Was Daniel's family provided with sufficient information to allow them to give informed consent to the procedure?

The evidence suggests that the family was not encouraged to seek a second opinion. They were offered the option of sending their child out of province. However, when they raised the prospect of bringing a surgeon to Manitoba, it was made clear to them that this was unnecessary, since there was nothing available outside the province that was not available in Manitoba. This amounted to a form of pressure to have the procedure carried out in Manitoba. The assurances given to the Terziskis about the competence of the Winnipeg team must be considered in light of the comments from witnesses. Both Duncan and Cornel said that it might not have been wise for the Winnipeg team to undertake a Norwood at that point in its history, and Soder commented on the role that surgical issues played in Daniel's death.

- Finding

As in other cases discussed above, Daniel's parents were not fully informed as to the fact that this was Odim's first Norwood, either without supervision or with expert assistance. Nor were Daniel's parents informed about the recent deaths of other patients in the program. This fact was of significance by this point, since many of the people involved in the program were clearly concerned about its mortality and morbidity rates. This evidence tends to suggest that Daniel's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Was Daniel healthy enough to undergo an operation?

- Finding

As noted above, there was in this case, as there had been in several other cases, concern on the part of the consulting witnesses that Daniel was taken to surgery with an infection. There appears to be some evidence to validate that concern. The concerns about infection with respect to the Caribou case and the Goyal case have equal application here.

Should the HSC team have attempted the operation or should Daniel have been referred out of province?

■ Finding

In the wake of the results in the Goyal, Caribou and Ulimaumi cases, and given Odim's lack of experience (coupled with the overall lack of planning), it was unwise to undertake this operation in Winnipeg.

Should there have been better planning for this procedure?

■ Finding

The evidence suggests that there was not enough planning for either the operation or the post-operative care.

Did the length of surgery contribute to Daniel's death?

Cornel, Duncan, Hudson and Soder all noted that the operation was lengthy and that this length could have compromised Daniel's heart. In their joint report, Cornel and Duncan wrote:

> There appear to be some questionable surgical management issues related primarily to the duration of bypass. We once again question the appropriateness of an inexperienced surgical team performing Norwood procedures. (Exhibit 354, page 6)

Soder indicated in his report for this Inquest that:

> **[T]he skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations. Surgical factors were the prime determinants of fatal outcome in 9 of the 12 deaths.** (Boldface in original) (Exhibit 345, page 8)

■ Finding

The case of Daniel Terziski was one of the nine that Soder identified in which surgical factors were a prime determinant in a fatal outcome. In particular, he identified the failed first repair and prolonged circulatory arrest time as major surgical factors and the prolonged bypass time as a minor factor. The evidence suggests that the length of surgery contributed to Daniel's death.

Was there appropriate post-operative care?

■ Findings

The evidence suggests that the neonatal intensive care unit was not properly prepared to deal with Daniel Terziski. Although staff in the NICU sought information from Odim before the operation, according to testimony, they only received vague responses. The fact that the neonatologist was not present when Daniel arrived from the OR indicates a breakdown in communication. It is also disturbing that the resident, and later Odim and Giddins, briefly left Daniel without a doctor being present at his bedside. In his written report Cornel noted that Daniel

should have received more monitoring of oxygen and carbon dioxide (blood gas analysis) and of the amount of potassium in his blood.

Cornel wrote that the "wisdom of managing complex open heart patients at two sites in the same small institution is questionable." (Exhibit 353, page 32) In his testimony, Cornel expanded upon this point, which referred to the fact that in Winnipeg, both the NICU and the PICU managed open-heart cases:

> It's not just in dealing with Norwoods, I would really need to know what their experience in dealing with post-operative open heart patients was. We do about 50 babies, or less from neonates—it would be less than that. And so for neonates, to accumulate the experience in post-operative management, for the neonatal intensive care unit to accumulate the post-operative management skills would take a long time. Especially with nursing shifts, you don't get the same nurses, it really spreads out the experience too much I think. (Evidence, pages 44,817–44,818)

In the coming months Odim did seek to have all open-heart cases managed by the PICU post-operatively.

What was the cause of death and was it preventable?

Because there was no autopsy, it is difficult to state with certainty the cause of death in Daniel's case. It is clear that the operation failed to alleviate Daniel's condition. It also appears the operation exacerbated the problems that Daniel was experiencing. This was due at least in part to the length of the operation. Daniel's heart defect meant that there was torrential blood flow through his lungs, severely taxing his single (left) ventricle. As a result, he started to develop heart failure, which led to a decrease in oxygen saturation and damage to the heart muscle itself. Daniel then underwent a prolonged operation, with a very long circulatory arrest time, which led to more damage to his already compromised heart. This further reduced his heart's ability to pump blood and the heart failed. The length of the TCA would have also caused some neurological damage to Daniel. With the heart failure came a resultant drop in blood oxygen, and a consequent decrease in oxygen delivered to the heart muscle. As Daniel's heart struggled to pump, his blood pressure decreased. The heart rhythm then became abnormal and he suffered a cardiac arrest.

- Finding

Given the fact that there was no autopsy and that Norwoods are a high-risk operation, it is not possible to provide a clear-cut answer as to whether or not this death was preventable. It is clear that the chances of preventing this death would have been increased if the child had been referred out of province.

WHAT HAPPENED AFTER THE TERZISKI CASE

After the Terziski case, the NICU management set about creating a cardiac bin similar to the one the PICU staff were in the process of establishing. An NICU nurse spoke with Odim and Hancock following the operation and created a list of equipment they might need in the unit. The NICU clinical instructor, Judy Wiebe, took the list and began to finalize the bin. Wiebe consulted with Youngson, Hinam and Plouffe from the PICU about their cardiac bin. The revised list was sent to Odim for a final approval. According to Armitage, Odim never provided any feedback. It was not until January 1995 that Wiebe spoke with Odim informally and got approval for the list of bin contents.

Following Daniel's death, Borton went to speak with her immediate superior, Lois Hawkins, about her concerns with the program. She also spoke with Giddins about her concerns over the surgical outcomes. She indicated that one of her concerns was the amount of bleeding that children were experiencing after surgery. According to Borton's testimony, Giddins indicated that Odim was part of a new, faster generation of surgeons and that one of the results of changes in technique was increased bleeding. Borton also testified that she asked Giddins to speak with Youngson about the events that were taking place during surgery. Borton said that she later asked Youngson if Giddins had ever approached her to discuss the events in surgery, and she said that this had never occurred.

Borton also came to a more direct realization of her concerns when the parent of a child who was to be treated at the centre asked her if she, Borton, would allow a child of hers to be operated on by the Winnipeg Pediatric Cardiac Surgery Program.

> I said, well, I really can't answer that because she's not my child, you know, I can't—well, I can't say that, I can't answer that because she's not my child.
>
> And, in fact, that was a lie, because I had always been able to say to people, in terms of support, to say to them before, Dr. Duncan could operate on my child. I don't have children, but if I did have children, he could operate on them. I had all that confidence, I was able to say that. (Evidence, page 18,177)

Borton was not alone in having grave concerns. In the following month two other nurses asked not to be assigned to pediatric cardiac surgery cases.

Giddins himself had a very different response to Daniel's operation. He told this Inquest that the Terziski case improved his assessment of the surgical team.

> That it was an extraordinarily heroic and difficult surgery, that I had seen on many occasions end with an unsatisfactory result in the operating room. This patient survived the operation.
>
> *Q:* But died an hour after?
>
> *A:* That's correct. Of circumstances that are difficult to be certain of, but most of the cases of that sort that I had had experience with before hadn't even made it to the NICU. (Evidence, page 3,760)

This is a disturbing comment. It is true that the Winnipeg program's success rate with Norwoods was very poor. It suggests that Giddins was gauging the team's progress along a learning curve, and the fact that child did not die in the operating room should be seen as a sign of the team's improvement. It is the case that surgeons do travel along a learning curve. However, there should be no allowance for a learning curve when analysing results of surgery where patient safety is concerned. Undoubtedly the two most effective tools in protecting patients as surgeons develop their skills are judicious case selection and careful preparation. Both were absent from the Winnipeg program in 1994.

THE RESULTS UP TO THAT TIME

Giddins's appreciation of the Terziski case aside, there was good reason to feel that the program was experiencing poor results up to that time. According to the records of the Variety Children's Heart Centre (Exhibit 62), from the time of Odim's arrival to the death of Daniel Terziski, Odim had operated on 18 children. Of those, nine underwent relatively minor closed procedures, and nine underwent open procedures where the CPB machine had been used. Of the nine in that second group of children, four had died.

ULLYOT MEETS WITH WISEMAN

Ullyot met with Wiseman on April 26 to discuss the concerns that the anaesthetists had brought to her attention. In preparation for that meeting she compiled a list of all the cardiac cases and their outcomes. According to her list, in addition to the four cardiac patients who had died, another was making a rocky recovery in the ICU. She gave this description of her meeting with Wiseman.

> I told him I wanted to talk to him about the pediatric cardiac cases, that the section, the people who were involved in providing anaesthesia for those cases were concerned that the mortality was high, and that the children who did survive had long ICU stays, and some of the complications seemed to be unusual.
>
> And he said something about, well, the mortality is not that high. I said, Nathan, the mortality is 30 to 40 percent. He said it's not that high. I said, well, here is the list of the kids, and I gave him this one. These are the children that had been done. (Evidence, page 31,245)

Ullyot was asked why she had gone to Wiseman with this information. She gave the following testimony.

> Two reasons; one is because I knew him very well and I worked with him on many committees, and he looks after cardiac, he looks after surgery at Children's. He's the real working head of cardiac surgery.
>
> The other question was, who else? Who else would you take it to? I suppose the only other person you might think of is taking it to Dr. Odim. And I particularly did not want to do that, because I felt that there was a sense within my department and nursing, and even outside of there, that we were suggesting that Dr. Odim was the whole problem. (Evidence, page 31,248)

Ullyot felt that the members of her department had been constantly questioning the way that Odim practised and raising concerns about communication. She thought the program was in need of repair, but she did not want to antagonize Odim at that point.

Ullyot said she left Wiseman a copy of her notes, but she did not question him about what he intended to do with them.

In his testimony, Wiseman said he did not recall being given the list at the April 26 meeting with Ullyot. However, the evidence seems to point to no other conclusion than that he did receive it when Ullyot said he did. She did not hear back from Wiseman before May 16.

Wiseman testified that during this period, he had a number of conversations with Odim about individual cases. He said that Odim was concerned about a number of the outcomes, but provided reasonable explanations. Aside from what happened in the Ulimaumi case, Wiseman testified that Odim had left him with the impression that there were no serious technical problems.

Wiseman did not pursue the matter any further with Odim.

MEETINGS IN LATE APRIL AND EARLY MAY

Boyle testified that within 24 hours of her April 28 meeting with Hinam, she spoke to Bishop about the concerns that had been raised. According to Bishop, she did not meet with Boyle to discuss the program until early May. Whether the meeting took place in late April or early May, Bishop confirmed that Boyle told her there were concerns with cannulation, bleeding, morbidity and mortality. In addition, she was told that the anaesthetists involved in the program had similar concerns.

Boyle testified that in May she also informed the vice-president in charge of nursing, Susan VanDeVelde-Coke, about the issues that the nurses had brought to her attention about the Pediatric Cardiac Surgery Program. VanDeVelde-Coke on the other hand, could not recall Boyle speaking to her about the PCS program until the fall of 1994.

Bishop testified that after Boyle had contacted her with concerns from the nursing staff about the program, she asked Wiseman for his assistance in determining how well-founded the concerns were. According to Bishop's testimony, Wiseman did not inform Bishop that any of the nurses and anaesthetists had already approached him. Wiseman again testified that he had no specific memory of that conversation with Bishop. However he did take steps to gather information for Bishop.

With regard to the conversations that Wiseman said he could not recall, he never denied that any of the conversations took place. In most instances, he accepted that in all likelihood they had taken place. He could not, however, recall them specifically. He apparently made no notes of them, nor of any action plan arising from them. This seems surprising, given the mounting tensions within the program, and the number of people raising concerns about what was occurring.

By mid-May, Wiseman had reported back to Bishop that he had spoken to the anaesthetists, Giddins, Hancock and a perfusionist. In addition, he had reviewed most of the cases with Giddins. He testified that following the death of Alyssa Still on May 6, Wiseman, as chief of pediatric surgery, requested a meeting with him. He said that he and Wiseman reviewed all the operations up to that point at that meeting. Giddins testified that he believed that Wiseman was satisfied with his accounting for the surgical outcomes. Wiseman, surprisingly, could not recall this meeting. Bishop testified that Wiseman anticipated speaking with a number of nurses before reporting back to her in full.

Bishop also spoke with Kesselman and Giddins. Kesselman was not prepared to assess Odim's surgical skills at that point. However, he did point to communication issues between Odim and two of the anaesthetists, McNeill and Swartz. Giddins, Bishop recalled, was very supportive of Odim.

Bishop said that she was attempting to develop a broad idea of the nature of the problems emerging in the program. She thought that it was possible that a review committee might have been set up once she knew what the problems were, but she admitted that there had been no plan to set one up when events overtook her.

NURSES SEEK REASSIGNMENT

As April progressed, some of the operating-room nurses began to express reservations about continuing to work in the program. According to Dixon, McGilton approached her and asked her if nurses could refuse to scrub in for pediatric cardiac surgery procedures. "They were hoping, I think, that they wouldn't have had to be part of the whole operative procedure." (Evidence, page 12,511)

According to Dixon, McGilton asked to be removed from pediatric cardiac cases. Dixon testified that a second nurse, Helen Skomorowski, also asked to be removed from such cases. However, for resource reasons, removing those nurses from the care of these patients was not possible.

On May 9, Dixon had a formal meeting with Wiseman where she told him that morale was low and there were problems with cannulation. She testified that Wiseman told her he did not think that Odim was having any greater problems than Duncan had experienced. In addition, she testified that Wiseman suggested that the program was on a learning curve as it adapted to a new surgeon. Again it appears that those assessing were applying the concept of a learning curve, although in this instance it is uncertain if the concept was being used to justify poor surgical outcomes or the ongoing conflicts between individuals.

In testifying about this meeting, Wiseman said:

> I perceived at that time that they were undergoing a kind of culture shock phenomenon, in the sense that they had for five years worked with one individual, and had a mindset of the way things were done. And you know, we tend to be creatures of habit, and when things are done differently, there is two ways we can approach them; we can sort of say, well, this is a different way of doing it and be a little I guess open minded about the advantages or disadvantage or value; or we can get to be old and crotchety like I am and not to be so flexible and think that my way is the best way. (Evidence, page 39,560)

From the evidence presented to this Inquest, it would appear that there was far more than culture shock involved. It would also appear, however, that the message that Bishop was receiving from Wiseman was simply that some members of the surgical team were having difficulty adapting to a new leader. That message failed to fully capture and report the depth of the problems facing the program.

ODIM'S VIEW

Odim was questioned as to whether or not outcomes in the Caribou, Ulimaumi and the Goyal operations raised concerns for him about how the team was working. He was also asked why it appeared that he had taken on all cases that came his way, regardless of level of risk. Odim said that he had never felt pressured into performing operations. Furthermore, he had been confident—based on his initial meetings with the team members—that the team could provide acceptable care to the children. After experiencing a number of tragic outcomes, he said that he still did not sense any major difficulties. He did say that he was beginning to have questions about the way in which team issues were being addressed.

> It was also becoming apparent that from day one nobody was really attending a lot of the team functions that were set up to build team spirit and community. The only real function that was attended was the cath conference before the cases in the week, so those things sort of were evolving in the first two months but I still felt and was still enthusiastic about making pediatric cardiac surgery work in Winnipeg. (Evidence, page 24,258)

Odim said that within a month and a half of his arrival, he started to make efforts to establish extra rounds because there "wasn't much of a team concept." (Evidence, page 24,273)

THE EXISTING ROUNDS AND CONFERENCES

In his testimony Odim said that he believed the M & M Rounds were an appropriate forum for reviewing case outcomes.

> It's usually been in the surgical arena when the cases are presented and things are discussed, that is the forum that those types of things come out. It sort of serves also as an audit function in addition to reviewing what one could do better, that type of thing. (Evidence, page 23,999)

The M & M Rounds were held once a month on Friday afternoon, although the timing of the meeting could vary. At the meetings there would usually be a presentation from Odim, Giddins or both. A wide range of people—medical students, nursing students, residents, pathologists and members of the pediatric cardiac surgery team—could attend M & M Rounds on a voluntary basis. There was generally a considerable delay between the time that an operation took place and the time it was dealt with at the rounds, particularly in the case of a death. This was to allow the pathologists time to have completed a post-mortem and to have prepared material for the presentation. McNeill gave this description of how the M & M Rounds functioned.

> They would go through a sort of a listing of the cases that had been done since the last M & M conference, and perhaps sort of outcomes, and also if there had been a problem involved with the case, how that had been handled or what had been the outcome of that. That was often a fairly, like a listing, you know, we wouldn't go case by case in depth, it would be done that way.
>
> And then there would probably be one or two cases that were presented in more detail. They could have been cases that were done relatively, like in the immediate past, or potentially a child that had had surgery three or four months before. (Evidence, page 12,916)

Anaesthetists often were not able to attend these Rounds. The Rounds were scheduled to start at 1500 hours and the anaesthetists were often in the operating room until 1530 or later. As a result, McNeill said, she attended only one or two Rounds in the spring of 1994.

Odim commented that the Winnipeg M & M Rounds were poorly attended and, as a result, the quality and substance of the discussion suffered.

Youngson could not recall if the cases of the children who had died were discussed at any of the M & M Rounds. Swartz testified that even if they had been presented, the types of issues that the anaesthetists wanted to discuss were not normally dealt with in M & M Rounds.

> Generally speaking, M & M rounds were run by Dr. Odim, and so these issues would not usually come up at M & M rounds.
>
> M & M rounds would be more to review the pathology, to review the nature of the surgery, the proposed procedure, what was actually carried out, the results, if there was morbidity or mortality, that sort of thing; but not to review technical difficulties. (Evidence, pages 15,778–15,779)

McNeill concurred with that view. She did not see the M & M Rounds as an appropriate forum in which to challenge the surgeon's approach to specific issues. She said this had also been true of the M & M Rounds when Duncan had been the pediatric cardiac surgeon. After the Goyal case, McNeill said, she had not considered taking her concerns to the M & M Rounds because she viewed it as essentially an educational venue.

Swartz testified that she also did not believe that pre-operative conferences provided the appropriate forum for discussing these issues, since they were focused on introducing the issues surrounding new patients. When asked if it would have been appropriate at such conferences to question if the program was ready to take on a specific operation, she answered that it would not have been.

It is clear that by the end of April, the Pediatric Cardiac Surgery Program was in serious trouble. The results from the procedures conducted to date were not good. An objective consideration might well have concluded that the team was not providing a level of care appropriate to the needs of the population of the province.

Additionally, two of the department heads and possibly one of the hospital's vice-presidents had been informed that the OR nurses and the pediatric cardiac anaesthetists had serious concerns about the program.

Some of the staff in the program were worried that the HSC was incurring potential civil liability in the way it was handling cases, and that when blame was being apportioned, it would fall heavily on them.

The surgical team existed in name only. The need for a cohesive collective approach to the treatment of children was badly missing, and little was being done to address that fact. Warnings had, in fact, been given—and by and large, they had either not been fully understood or had been ignored.

THE CASE OF ALYSSA STILL

ISSUES

Alyssa Still died on May 6, 1994, following surgery on May 5. Her case gives rise to the following issues:

- Was Alyssa's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Alyssa healthy enough to undergo an operation?
- Were there technical problems with the operation?
- Was the PICU adequately equipped for her case?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Alyssa Still, the firstborn child of Donna Still, was born at 39 weeks gestation by caesarean section in Thunder Bay, Ontario on November 14, 1993. Shortly after her birth, her doctor, Dr. G. Derbyshire, diagnosed Alyssa with a heart murmur. An ultrasound indicated that she had Tetralogy of Fallot. Donna Still said that she understood Tetralogy of Fallot to be a large hole in the heart, which would simply not close.

Derbyshire was familiar with Giddins, and referred the Stills to the Variety Children's Heart Centre. He advised Donna Still that Alyssa would probably have to undergo heart surgery. Donna Still and her mother, Shirley Mae Still, took Alyssa to Winnipeg in March 1994. Donna Still indicated in her testimony that she had been given the option of going to Toronto with her child, but had chosen to come to Winnipeg because it was closer to Thunder Bay. Once referred here, there was never any suggestion that the operation be performed outside Manitoba.

THE DECISION TO OPERATE

Giddins saw Alyssa at the VCHC on March 18, 1994. An echocardiogram performed that day revealed Tetralogy of Fallot, with:

- mild biventricular hypertrophy
- a non-restrictive subaortic ventricular septal defect
- a three-millimetre (in diameter) mid-muscular ventricular septal defect
- moderate muscular right ventricular outflow tract obstruction with thickened pulmonary valve leaflets.

The diameter of the bicuspid pulmonary valve was eight millimetres. The bilateral proximal pulmonary arteries were narrowed to five to six millimetres in diameter.

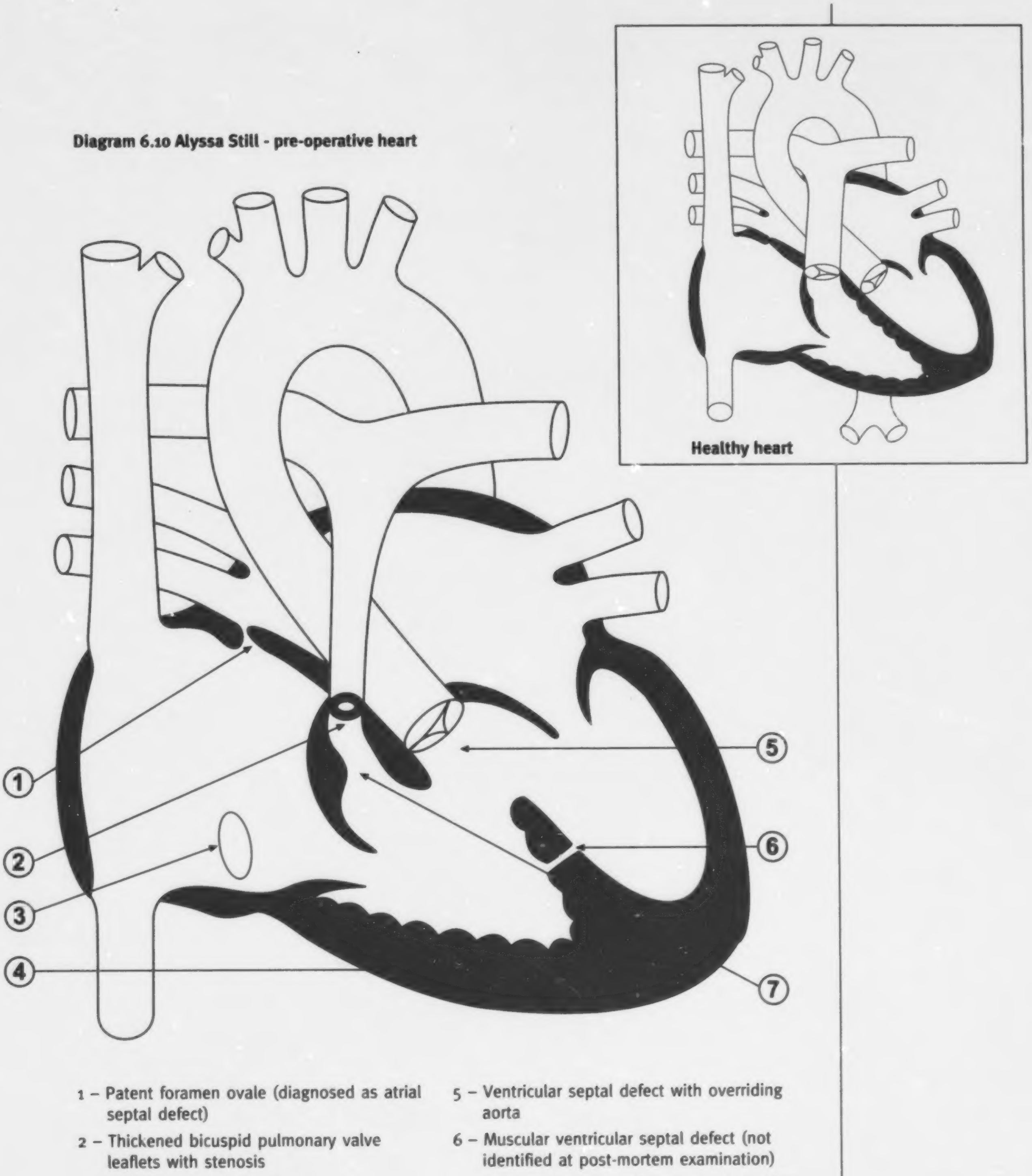
A chest X-ray done on March 18 showed that Alyssa had an enlarged heart. According to radiologist Dr. A.C. Patton, there was no evidence of acute pulmonary infiltrates. This is the term for the white areas on X-rays of the lungs. Infiltrates are also referred to as densities. The absence of infiltrates indicated that the lungs were normal. In subsequent testimony, Dr. Martin Reed, the head of pediatric radiology at HSC, indicated that he believed the X-ray actually revealed a mild abnormality.

Giddins advised that surgery was required in the near future. While the Stills had been told that an operation would be necessary, they did not expect that it would take place so quickly. Donna Still testified that the nature of the problem was explained. She was left with the sense that she had no real choice but to proceed with the operation. While Odim was not present at this meeting, Still testified that Giddins told her Odim was one of the best surgeons in North America. She said that she was left with the impression that, while Odim was new to the hospital, he had worked—as opposed to trained—in Boston and Montreal. She also said that Giddins indicated to her that the success rate for this procedure was 95 per cent.

Four days after Giddins met with the Stills, Alyssa's case was presented at a CVT conference involving Odim and Giddins, as well as staff from the Heart Centre. After the conference, Odim outlined his conclusions in a March 22 letter to Giddins. Odim described Alyssa as a four-month-old child whose evaluation confirmed the picture of Tetralogy of Fallot. She had no obvious symptoms of heart problems and was not taking any medications. He mentioned that the chest X-ray showed clear lungs and a slightly enlarged heart. His conclusions differed from Giddins's. Odim had detected an atrial septal defect, while Giddins reported that there was an intact atrial septum. Odim wrote that his view was that the child needed early repair and that he would be happy to discuss the operative approach and risks with the family (Exhibit 11, page STI 1).

On March 22 Giddins wrote to Derbyshire that "Alyssa has Tetralogy of Fallot, with an atrial septal defect and significant obstruction at both the sub-pulmonary and pulmonary valve level." (Exhibit 11, page STI 2) Giddins stated that "Her muscular ventricular septal defect is likely not significant, and overall my impression is one of anatomy highly favourable for definitive early correction. The nature of the problem was explained to the family, as was our tendency to operate before six months of age, a concept they agreed with." (Exhibit 11, page STI 2)

Diagram 6.10 Alyssa Still - pre-operative heart



1 – Patent foramen ovale (diagnosed as atrial septal defect)

2 – Thickened bicuspid pulmonary valve leaflets with stenosis

3 – Opening to coronary sinus

4 – Right ventricular hypertrophy

5 – Ventricular septal defect with overriding aorta

6 – Muscular ventricular septal defect (not identified at post-mortem examination)

7 – Right ventricular outflow tract obstruction

CONSENT

Odim testified that, in his conversation with the Stills, he had outlined Tetralogy of Fallot and discussed the ways in which the condition could be treated.

> We discussed the surgery in detail in terms of what needs to be done, how it is—how it is done using the heart-lung machine. We discussed the issues of the risk and what types of problems that one can encounter, both being on the heart-lung machine and from the actual repair and told her that essentially in terms of numbers, you take a hundred people like Alyssa, that 90 to 93 will leave the hospital. (Evidence, page 24,925)

As his note suggests, there was no discussion of treatment outside Manitoba, nor of the team's lack of experience. The Stills did not apparently raise any questions about the team's experience with this procedure. This was not surprising. However, Odim and Giddins failed to inform them of the surgeon's lack of experience with this procedure in an unsupervised setting.

The Stills then returned to Thunder Bay to await the scheduling of the operation. Upon her return to Thunder Bay, Alyssa developed a cold. Donna Still took her daughter to the emergency ward of McKellar Hospital in Thunder Bay on April 1. There she was given a prescription for an antibiotic for one week.

The operation was set for April 21. The Stills (Shirley Mae, Donna and Alyssa) returned to Winnipeg on April 17.

PRE-OPERATIVE CONDITION—FIRST ADMISSION

On April 18 Alyssa was admitted to the HSC. A nurse on the cardiac surgical ward noted that Alyssa tired easily, especially during meals. She also noted that Alyssa had a congested cough.

That same day, a physiotherapist assessed Alyssa's pre-operative respiratory status. Donna Still told her that the baby still had a congested-sounding cough following her cold. On examination, the physiotherapist heard breath sounds equally in both lungs. She also heard a low-pitched expiratory wheeze, which was greater in the right upper lobe of the lungs than the left upper lobe. She concluded that Alyssa was not in respiratory distress, but had some upper airway congestion.

The findings of an April 19 heart catheterization confirmed previous studies and measured a large VSD. Specifically Alyssa had an acyanotic Tetralogy of Fallot with a small muscular VSD, in addition to a large subaortic VSD. There was severe sub-pulmonary muscular obstruction, pulmonary valve stenosis and mild right pulmonary artery stenosis. The coronary arteries appeared normal. At the end of the catheterization report, Giddins wrote, "Case to be discussed with the surgical team within next 24 hours." (Exhibit 11, page STI 147)

While Alyssa was in hospital, her mother and grandmother met with Odim. Donna Still testified that the heart problems were explained and she was left with the sense that the operation was common and usually successful. Again, it would appear that there was no discussion of the surgical team's experience.

A nurse recorded on the evening of April 20 that she had completed pre- and post-operative teaching with the child's mother and grandmother. She commented that both women asked questions and seemed to understand the information given to them.

That evening, Giddins and Odim concluded that in view of the recently resolved respiratory infection and the right middle lobe infiltrates seen on the chest X-ray, the operation should be postponed for two to three weeks (Exhibit 11, page STI 149). In his testimony, Odim said:

> At the point at which this was brought to my attention, which was in the evening, Dr. Giddins and his staff had spent time with the mom and patient and gotten a history, and examined the patient, and they were of the opinion that given a history of pneumonia, or some pneumonic process, and their own clinical assessment, they felt that they wanted to postpone the case. And when he brought that to my attention, he took me down to take a look at the films, and I went on with his—concurred and deferred to his clinical judgment. (Evidence, page 24,874)

The next day, April 21, Alyssa was discharged to Ronald McDonald House to await surgery. The discharge summary noted that while Alyssa was afebrile and had good air entry in her lungs, when she breathed she did have some abnormal sounds in her upper airways and a "rattly cough." (Exhibit 11, page STI 150)

PRE-OPERATIVE CONDITION—SECOND ADMISSION

Odim met with the Stills on May 2. At that meeting, Donna Still signed a consent form. Following that meeting, and after examining an X-ray taken that day, Odim wrote to Giddins that:

> As you know, she had originally been placed on the schedule a little over a week ago but was recovering from an upper respiratory tract infection and had evidence of a right middle lobe infiltrate necessitating postponement of surgery. In the intervening period she has been well without evidence of infection. She still has a cough. There is no catarrh [no runny nose]. The chest X-ray today shows clear lung fields and a bulky heart. There are some residua of middle lobe infiltration. We plan to get a nasopharyngeal swab to check for RSV and if this sample is negative I think we can proceed with definitive repair later this week. (Exhibit 11, page STI 6)

The radiologist had a different interpretation of the May 2 chest X-ray. While Odim wrote that it showed clear lung fields, Dr. Martin Reed recorded in his report that:

> There is slightly more consolidation in the right perihilar region extending into the lower lobe, than on the previous examination of March 18. Abnormal densities persist in the left lower lobe as well, essentially unchanged. The appearance of the heart is not changed in the interval. Interpretation: the pneumonia appears slightly worse. (Exhibit 11, page STI 62)

The reference to pneumonia was to become a troubling one in the investigation of this case.

In coming to this conclusion, Reed had to have determined that the March 18 chest X-ray had indicated that Alyssa had mild pneumonia, while the May 2 X-ray showed that the pneumonia had slightly worsened. Reed, in other words, was making a different interpretation of the March 18 X-ray and the May 2 X-ray. Reed also testified that he did not believe her pneumonia was an unexpected abnormality, in light of the cancellation of surgery two weeks earlier because of an infection.

Reed's report was written and distributed on May 4, the day before Alyssa's scheduled operation. It does not appear that either Odim or Giddins read this report before Alyssa's surgery. Nor were the Stills made aware of Reed's report.

Odim on the other hand did not believe Alyssa had pneumonia. He testified that:

> With all due respect to Dr. Reed, he didn't have the advantage of hands-on contact with the patient. The patient had no symptoms, had no signs of pneumonia, was afebrile, white count was normal, if you look at the laboratory data, no leftward shift, no indication of any infectious process. (Evidence, page 24,886)

Anaesthetist Dr. Harley Wong also disagreed with the assessment that Alyssa had pneumonia before her operation. He noted that there was no sign of a fever and that her white blood cell count, which would have been elevated if she had pneumonia, was normal. He also indicated that during the induction of anaesthesia, Alyssa did not exhibit the symptoms that one would expect from a child with pneumonia.

> If the child had that pneumonia when the child came into the room and we put the child asleep, there would have been a couple of problems that we would have had to deal with right away if the child had pneumonia. First of all, we would run into problems with secretions, tremendous amounts of secretions. If the child had pneumonia, I would have had to have been suctioning the child for a lot of secretions if there had been pneumonia, and I would have had problems dealing with keeping the child well oxygenated. I would have had drops in oxygen saturations that were unexpected. I would have difficulties ventilating the patient.
>
> I can add to that that I have seen that in patients that were brought to the operating room with pneumonia in other cases, for other reasons, that did have pneumonia, and that's exactly what we experienced. (Evidence, page 19,812)

Wong went on to testify that if Alyssa had had pneumonia, she would have not had the stable blood gas and oxygenation readings she had during the early portion of her stay in the PICU post-operatively.

In this case, as in several of the cases that preceded it, questions arise as to whether or not the patient had an infection at the time of surgery. In his report for this Inquest, Cornel wrote:

> A pulmonary infection 2 weeks prior to surgery may not have completely cleared (cough reported by mother and physiotherapist on 4th May). (Exhibit 353, page 37)

Cornel pointed out that Alyssa's post-operative arrest was related to suctioning of secretions that might have been related to the infection. He stated that:

> In my practice these finding [sic] would constitute a contraindication to all but the most urgent surgery, and if I must operate in the face of active infection I usually perform a palliative rather than open heart surgery. (Exhibit 353, page 39)

Witnesses before this Inquest could not be definitive about the pre-operative state of Alyssa's lungs because X-rays were missing from the files. The report prepared jointly by Duncan and Cornel also commented on this issue.

> Similarly, the pre-operative chest radiograph is reported as showing pneumonia, which would normally be an indication to cancel and reschedule the surgery unless the child was in imminent danger of death without proceeding. The absence of this radiograph from the master file of radiographs is disconcerting. (Exhibit 354, page 8)

However, in their testimony, both Cornell and Duncan acknowledged that Odim might have been correct in sending Alyssa to surgery in May. Duncan explained that sometimes an X-ray does not show what the patient has at that point but what the patient had in the past. In other words, the patient may have recovered from a clinical point of view, while the X-rays show evidence of the lung in the process of healing, rather than showing an active infection. Dr. Walter Duncan testified:

> I don't know if you have ever seen two physicians who could agree about anything, but, no, it's not unusual to have differing opinions. And whereas the radiologist only sees the film, the physician sees the patient. So I think perhaps one is, one tends to be biased to one's point of view, I mean, that's human nature, isn't it?
>
> Dr. Odim would have seen and examined the child, listened to the chest and looked at the x-ray and said, well, I don't hear anything in the chest, she seems to be fine, her white cell count is normal, I think I am okay to proceed.
>
> A radiologist would look at a film, compare it to a previous film and say, film A looks different from film B because—was that grounds to cancel? I think you could argue it both sides. (Evidence, page 41,384)

In conclusion, Duncan testified that in this case he did not "think there was sufficient grounds to cancel." (Evidence, page 41,388) Cornel came to a similar conclusion, testifying:

> In the absence of anything else, I would accept their view of things. I am always concerned about respiratory infections, as I keep saying, and I would be concerned if an x-ray was taken as a follow-up for pneumonia and nobody paid attention to it. But in the absence of any other findings, I accept what they say, that there was no evidence of an active infection and it was okay to go ahead. (Evidence, pages 44,828–44,829)

In his written report, Hudson stated:

> Proceeding with an elective operation with a coexisting unresolved pneumonia is definitely not an acceptable standard of medical care. The only exception to this rule would be a patient who had chronic respiratory infections that could not be successfully treated, and there is nothing in these records to indicate that was true of this patient. There is not unanimity of opinion regarding the length [of] time elective surgery should be delayed after resolution of a pneumonia. However, any competent physician would agree that elective surgery should not be done when any clinical or radiographic signs of pneumonia are present. The fact that the chest radiograph was ordered by the attending cardiologist on 2 May 94 suggest that he was still concerned about the pneumonia. However, there is no evidence in this patient's records that any of the physicians involved in the perioperative management of this patient were aware of the radiographic findings indicating a worsening pulmonary infection. (Exhibit 307, pages 5.20–5.21)

Consulting witness Dr. Glenn Taylor reviewed the microscopic slides and also concluded that the lungs were moderately congested with irregularly expanded air spaces. He found no evidence of acute pneumonia. In a May 5, 1997, letter, Taylor said:

> I did not see acute pneumonia in the autopsy microscope slides of the lungs that were sent to me. It is possible the sampling of lungs at autopsy missed areas of pneumonia, although 5 specimens from the lungs were examined. If pneumonia was present, it likely was focal. However, even mild acute pneumonia could adversely affect a child's recovery from open heart surgery. (Exhibit 336, page 5.6)

Taylor testified:

> Again, previous experience with children who have had open heart surgery, have good anatomic heart repairs, have good cardiopulmonary bypass runs, come into the ICU with no minimal or inotropic support, and then start to develop problems, generally pulmonary hypertensive crises. I think that's where mild degrees of pneumonia or pneumonitis or bronchiolitis play a role, is that these young children have very reactive airways, very reactive pulmonary or lung blood vessels, and if there is hypoxia, acidosis, the vessels can constrict down, you get into episodes of episodic pulmonary hypertension and a positive feedback system, because the blood vessels cramp down, blood flow to the lungs diminishes, and the child becomes more hypoxic and cyanotic, that causes further constriction of the blood. (Evidence, pages 43,102–43,103)

In short, while Taylor did not find pneumonia in the material he examined, he could not rule it out completely. Furthermore, he believed that pneumonia could account for Alyssa's post-operative experiences.

In his testimony to the Inquest, Reed said that upon consideration of Taylor's report and the testimony of Odim and Giddins about Alyssa's pre-operative condition, "I think it is reasonable to conclude that the patient did not have an active pneumonia on May 2nd." (Evidence, page 37,425)

ALYSSA'S ADMISSION TO THE CHILDREN'S HOSPITAL

Alyssa was admitted to the HSC on Tuesday, May 4. The admitting nurse wrote that her chest air entry was good but she had an occasional dry cough. The admitting medical student charted that Alyssa's chest was clear, with good air entry in both lungs. The physiotherapist assessed Alyssa's respiratory status in the afternoon. Alyssa's chest again sounded clear, although Alyssa's mother told the physiotherapist that Alyssa still had a congested cough in the morning and evening.

At 1600 hours, Wong assessed Alyssa's condition in preparation for surgery. On the consultant's report, he wrote, "Acyanotic but potential for cyanotic episodes exist. ASA II. Acceptable risk for GA [general anaesthetic]. In good condition." (Exhibit 11, page STI 49)

That evening Alyssa's mother and grandmother toured the PICU as part of the pre-operative preparation for surgery.

In her testimony, Donna Still said that on May 4 she had reservations about going through with the operation. That day Alyssa had become very upset when a blood sample was taken. Donna Still expressed her concerns to a nurse, although she could not recall which nurse she spoke to.

> I said I had a bad feeling about this surgery. Like I wasn't sure if I really wanted to go through with it. They made it perfectly clear that it had to go through, that there was no discussion otherwise. (Evidence, page 2,250)

Shirley Mae Still also testified to this hesitation. She said that she thought either Giddins or Odim was present and persuaded them to allow the operation to proceed.

In the early morning hours of May 5, 1994, as Alyssa underwent her final preparations for surgery, the nurse wrote, "...occasional congested cough noted overnight (no) nasal discharge." (Exhibit 11, page STI 40)

THE OPERATION—MAY 5

Alyssa underwent a complete repair of Tetralogy of Fallot. This included the placing of a Dacron patch over the subaortic ventricular septal defect, an interrupted suture closure of a small muscular ventricular septal defect, dilation and patching of the pulmonary arteries and valve, and excision of the right ventricular muscle bundle. Essentially, Odim patched the hole between the two pumping chambers and relieved the obstruction to her right pump. Odim testified that he did not see a still-smaller VSD that had been identified pre-operatively on the echocardiogram. Since such VSDs tend to close on their own, Odim was not concerned that he could not identify it. The PFO was left open.

The operating team is set out on the accompanying chart.

TABLE 6.11: Persons involved in the operation on Alyssa Still, May 5, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	B.J. Hancock
Anaesthetist	H. Wong
Scrub nurses	S. Scott, A. Glenday
Circulating nurses	C. Youngson, M. Arroz
Perfusionists	M. Maas, D. Smith

The myocardial protection used was moderate hypothermia and intermittent cold blood cardioplegia.

TABLE 6.12: Length of phases of the operation on Alyssa Still, May 5, 1994

Phase of the operation	*Time taken*
Induction	2 hours
Bypass	3 hours 7 minutes
Aortic cross-clamp	1 hour 1 minute
Total surgical time	5 hours 30 minutes
Total operating-room time	7 hours 40 minutes

Dr. Walter Duncan described the pump run as being long.

Alyssa apparently suffered Tet spells before cardiopulmonary bypass was instituted. Cornel and Duncan indicated in their reports that these spells occurred during induction. In his testimony, Wong said that the Tet spells were minor and occurred when the heart was being manipulated for bypass. The anaesthetic record showed that the Tet spells occurred after induction of anaesthesia and before going on bypass and during the induction of bypass.

Wong also testified that he believed that, while lengthy Tet spells could be a precursor to a difficult peri-operative course, Alyssa's spells were very transient and were treated with neosynephrine. Dr. Walter Duncan testified that, regardless of the triggering event, Tet spells could lead to a difficult recovery period. At the same time, he said that the appropriate course of action at that point was to proceed with the operation. Odim testified that he was not aware until after the operation that the spells had taken place.

No other problems arose during the procedure. Indeed, Youngson testified that she was thrilled by the outcome in the OR.

> The surgery, the repair seemed to go very well, if I remember correctly. And I remember we all felt really good, like, finally, we have got a case here that had gone well. The patient seemed to come out of it in very good condition, she was pink, vital signs I think were good, and she went to PICU, and everybody—I remember going home that night and thinking, well, good, this was good. (Evidence, page 8,439)

In his operative report, Odim wrote that following surgery, "The patient returned to the Pediatric Intensive Care Unit in excellent and stable condition." (Exhibit 11, page STI 54) As later events demonstrate, this was an overly optimistic assessment.

During the course of this Inquest, consulting witnesses questioned whether or not Odim's operative approach had provided adequate relief of the obstruction of Alyssa's right (pulmonary) valve. In his operative report, Odim indicated that he dilated the pulmonary valve to 10 millimetres, which he considered sufficient:

> The initial sizing of the pulmonary valve accepted only a 7 mm Hegar dilator. This was gently dilated up to 10 mm using the Hegar dilator. At this juncture, it was felt that given the child's age and weight that a 10 mm orifice would be sufficient and as such we elected not to do a transannular repair. (Exhibit 11, page STI 53)

In short, Odim determined that the valve was sufficiently enlarged. Therefore he did not think it was necessary to perform a transannular repair, in which the annulus is sliced and patched to enlarge the valve.

This view was questioned by Cornel, who testified that when he examined the heart, he thought the annulus was small and the pulmonary valve leaflets were not properly formed (or dysplastic). He believed that a valve of this nature would have represented a significant obstruction to blood flow. He acknowledged that "it is hard to be certain but this may represent inadequate relief of the pulmonary stenosis". (Exhibit 353, pages 36–37) He said that he would have conducted a transannular repair and that would have created a larger passage.

Taylor also thought the valve was small, although he said it was not significantly narrowed. He also raised issues about how well the valves themselves worked:

> The issue might be, is it a regurgitant or incompetent valve, because with distortion of the cusps or the three flaps of the valve, it may not close properly, and it may allow blood to fall back from the pulmonary artery into the right ventricle. (Evidence, page 43,097)

Taylor also indicated that the best way to assess the competence of the valve would be with an intra-operative echocardiogram, but one was not performed. HSC pathologist Dr. Susan Phillips agreed with Taylor that the valve was dysplastic and bicuspid. With regard to Cornel's reservation about the degree of relief of the pulmonary valve stenosis, Phillips testified that the size of the valve opening was not the only fact that had to be taken into consideration. It was also important to know the pressure measurements, and these could best come from an echocardiogram.

> If you are only using size, but size doesn't necessarily tell you how it's functioning. For that you need to have the clinical input, pressure measurements, whatever information they had prior to death. The size is only one aspect of a valve. For example, these valves were dysplastic, they may not have been functioning properly. (Evidence, pages 42,180– 42,181)

In summary, Odim undertook a surgical approach that did not involve removing or repairing the dysplastic valves, as he would have done if he had performed a transannular repair. It is unfortunate that an echocardiogram was not performed during surgery. Alyssa's post-operative problems could have been related to inadequate relief of pulmonary valve obstruction. If this was the case, an echocardiogram might well have provided HSC staff with valuable information.

However, it also appears that Odim employed one of a number of appropriate approaches to this operation.

POST-OPERATIVE COURSE

On admission to the PICU, Alyssa was very puffy, especially around her eyes. Her fluid balance at the end of bypass was 800 millilitres more than it had been at the start of the operation. Such a degree of fluid overload would make ventilation more difficult and would also make the heart muscle stiffer.

Alyssa was placed under a warming blanket because she was very pale and her arms and legs were cool, with pulses that were only weakly felt. Her blood pressure was moderately decreased and the output from her heart was low. The admitting nurse noted that her air entry was clear but decreased on the left side. Alyssa had a metabolic acidosis, which was being treated with sodium bicarbonate. She was also making occasional jerking movements of her chest. Kesselman testified that the jerking was most likely the result of one of the anaesthetic drugs wearing off.

While Odim had described Alyssa as being in stable and excellent condition on admission to the PICU, Kesselman gave a different perspective in his testimony.

> Well, she was, based on those findings of somewhat impaired cardiac output and edema and everything, she was not—I was going to say critical, she wasn't critical in the sense that things were changing, but she needed close attention, and gradually improved over the next several hours.
>
> *Q:* Was she stable when she came to ICU?
>
> *A:* Stable in the sense that nothing was changing, yes, but things were not as perfect as one would like, but I would say that her condition was adequate and not unexpected for a post-op repair early on. (Evidence, page 33,957)

In the radiology report of a chest X-ray taken post-operatively in the PICU, Reed noted, "The heart is normal in size. There are abnormal densities throughout most of the right lung, but the left lung looks essentially clear. Interpretation: There are abnormal densities in the right lung, which probably represent retained secretions." (Exhibit 11, page STI 63) In his testimony, Reed said that:

> It is quite common to see abnormal densities in the lungs following general anaesthesia, particularly if the surgery lasts for awhile. It is not surprising to see it after cardiac surgery. (Evidence, page 37,421)

He said that the densities were not likely to be pneumonia.

During the evening and most likely before 2000 hours (there is no time on the note) Giddins wrote, "Probably fluid overloaded with high likelihood of pulmonary edema." (Exhibit 11, page STI 46) He noted that Alyssa was quite puffy, with an increased heart rate of approximately 160. He suggested that the dose of dopamine be adjusted downwards and a diuretic started within 12–14 hours.

At 0100 hours on May 6, Colleen Kiesman, who was the bedside nurse, noted that Alyssa had a strong cough when she was suctioned. This procedure involves inserting a catheter through either the patient's nose or mouth to suction secretions out of the airways. If the patient is intubated, the catheter is slid down through the endotracheal tube. Because of the secretions in Alyssa's lungs, it was necessary for the nurse or a respiratory therapist to suction her airways. In the instructions for treatment that were left by Odim, there was no indication that Alyssa should be provided with any special treatment before being suctioned.

Odim said he did not believe Alyssa's cough at 0100 hours was related to her pre-operative cough. Nor did he think that the thick secretions that were being suctioned were related to the pre-operative condition. He said the more frequently a patient is suctioned, the less likely it is for the secretions to be very thick. Kesselman also testified that "Anyone who has a tube in and is suctioned is going to cough." (Evidence, page 33,960) He also testified that thickened secretions were not abnormal in this situation.

In a later entry note, Kiesman wrote that Alyssa was stable until 0342 hours, when she opened her eyes and started coughing. A respiratory therapist hand-ventilated her while Kiesman suctioned out a small to moderate amount of blood-tinged, thick secretions (Exhibit 11, page STI 48). Alyssa's heart rate and blood pressure began to drop. Kesselman was called to her bedside. At that point, the respiratory technologist was hand-ventilating Alyssa. Kesselman checked Alyssa's airway and chest for blockages and could not detect any. At this point Kesselman connected the pacemaker:

> All the children post-operatively have transthoracic pacing wires that are taped to their chest if the need for pacing should arise. So you have to disconnect these, they are taped in place, you take the tape off and connect the leads to the pacemaker box. And so I would have done that and turned the pacemaker on, which is just flicking a switch and turning a dial to turn it to full output. And with that there was no response in the heart rate, in that the pacemaker didn't capture the heart, meaning it didn't—the electrical impulses from the pacemaker box didn't cause the heart beat to stimulation. (Evidence, pages 33,962-33,963)

Kesselman initiated external cardiac massage at 0350 hours. At that point, the heart rate was 23 beats per minute. In addition, medication was delivered in an attempt to stimulate the heart. Odim arrived at 0406 hours and opened the chest four minutes later. He began internal cardiac massage at 0414 hours.

Odim also requested epicardial pacing wires and an internal defibrillator. These were not kept in the PICU. Youngson testified that she received a phone call at 0400 hours from a PICU nurse who was looking for pacing leads in the OR. She was also looking for internal defibrillator paddles. The wires were located and attached; however, the pacemaker still did not capture Alyssa's heart.

Those at Alyssa's bedside attempted defibrillation once at 0423 hours and three times at 0429 hours. At 0430 hours on May 6, the Stills received a phone call at Ronald McDonald House. They immediately went to the hospital where they were met by Odim, who told them Alyssa was in trouble. At 0501 hours, resuscitation was stopped. Alyssa was declared dead.

According to Kiesman's testimony, Odim then said that it was the suctioning that caused the cardiac arrest. Kiesman testified:

> I probably turned white, being the bedside nurse. But Dr. Kesselman had said that wasn't my fault after Dr. Odim had left, Dr. Kesselman said that he didn't know whether he would have done anything different in the situation. (Evidence, page 32,294)

Kesselman testified that he recalled hearing Odim tell Kiesman that it was the "suctioning that did it." (Evidence, page 33,984) Kesselman testified that he then reviewed the bedside monitor to determine if there were unappreciated events before the arrest. He said that he could not find any.

Did suctioning contribute to Alyssa's problems?

One of the central questions in this case is whether or not the suctioning was the cause of Alyssa's death. Odim testified that he never made any statement to Kiesman that her actions were responsible for Alyssa's death. However, this was how both Kiesman and Kesselman understood his comments. Clearly, they were left with the impression that Odim felt that Kiesman had done something wrong. As a result, Kesselman, who believed that Kiesman had not contributed to the death, felt compelled to try to reassure Kiesman.

Kiesman also testified that after Alyssa died, Odim asked her and Kesselman if Alyssa had been treated with atropine before being suctioned. Kiesman said that Odim indicated that if Alyssa had had such treatment, she might not have developed a slowing of her heart rate. Kiesman said that no such treatment had been given, nor had it been ordered, nor was it standard procedure in the PICU. Kesselman could not recall the conversation. He did indicate that the PICU would not normally have pre-treated Alyssa with atropine, since it would increase the heart's energy consumption. Odim testified that it was his experience that anaesthetists pre-treated with atropine. He also indicated that he believed Alyssa had been treated with atropine during the period when Kesselman was trying to revive her. Soder testified that atropine is used to prevent vasovagal episodes under what he described as very rare circumstances.

It is noteworthy that the medical chart does not indicate that atropine was either ordered or administered to Alyssa at any point that evening. It seems reasonable to conclude, for the reasons cited by Soder, that it was not something that was given to patients as a matter of course.

Odim's comments left Kiesman with the impression that she might have contributed to Alyssa's death. There is no reason to believe that that was in fact the case. There is a considerable body of evidence to suggest that patients who are intubated will experience coughing spells in conjunction with suctioning. There is also medical evidence to support the conclusion that the administration of atropine was not something that was done as a matter of course. There is nothing in the evidence to suggest that the manner of suctioning that Kiesman used for Alyssa that evening was out of the ordinary. Finally, there is evidence that the failure of the pacing wires to assist the heart to capture a proper rhythm was the most serious issue that the team faced that evening. The failure of the pacemaker or pacing wires to perform properly was a recurring complaint that ICU staff had about Odim's patients.

Shortly after 0501 hours, Odim met with the Stills. He told them that the problems started when Alyssa started coughing, and her heart started to slow down. Odim said:

> I think we were all very, very shattered and disappointed because she had been doing so well and the mom was there and I think the grandma was there and we were all shaking our heads. We couldn't understand what had happened.
>
> I tried to relay the events of the evening to mom and grandma and what we tried to do to reverse things, but we really were not—we were at a loss for an explanation save potential vasovagal response from suctioning and and/or pulmonary hypertensive crisis that we couldn't turn around. (Evidence, pages 24,921–24,922)

Donna Still consented to an autopsy. The Stills left Winnipeg on May 7, 1994. At the time no one could explain to her why her daughter had died. On the Sunday following their return to Thunder Bay, Giddins called and spoke to Shirley Mae and expressed his sympathy.

AUTOPSY FINDINGS

The final report of the autopsy, which was conducted by Dr. Susan Phillips of the HSC, was released on June 29, 1994. The autopsy did not identify a cause of death. Her report indicated that the repair was intact. In addition she identified:

- the presence of a suture in the coronary sinus;
- contraction band necrosis; and
- widespread edema, including swelling in the brain, the lungs and the heart.

Various consulting witnesses before this Inquest discussed these findings, which bear comment. It should be noted that these witnesses not only reviewed Phillips' report; they also examined Alyssa's heart.

The presence of a suture in the coronary sinus

In his operative report, Odim stated that he closed a small VSD with an interrupted suture. In her autopsy report, Phillips stated that she could not identify the VSD or the suture that Odim reported placing over it. This is disturbing. It is very unlikely that Phillips would not have been able to detect such a suture if it was indeed present in the heart.

At the same time, Phillips did record finding an interrupted suture "in the region of the coronary sinus. The coronary sinus is patent." (Exhibit 11, page STI 24) Odim recorded making use of an interrupted suture in closing the VSD. This gives rise to the possibility that the suture found in the region of the coronary sinus was in fact the suture that Odim intended to place over the VSD.

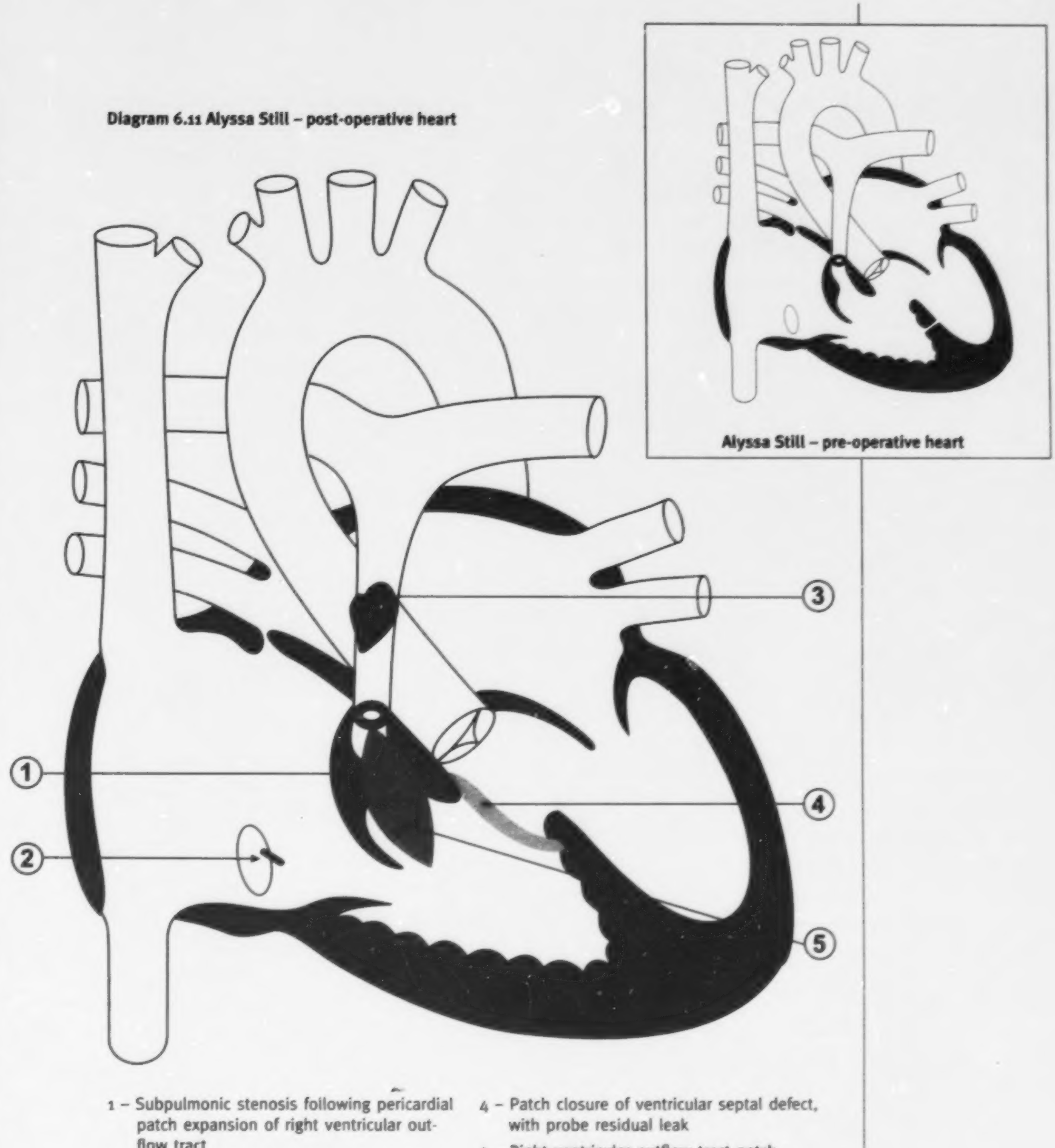
While this appears possible, there is a larger question. Did this suture close the sinus? The coronary sinus drains blood from the coronary veins, which in turn drains the heart muscle. If the coronary sinus were sutured closed, then the heart muscle would not drain properly. Taylor testified that the effect of a closed coronary sinus depends on the extent of the connection between the venous system and the ventricles of the heart. If there were few or no direct connections, an obstruction of the coronary sinus would interfere with venous return from the heart muscle. This could cause the heart to swell, leaving the child with edema or congestion in the heart muscle. The outcome would be impaired function of the heart. Because the connections are microscopic, it was not possible in Alyssa's case to determine whether there was adequate accessory venous drainage into the ventricles or the atria itself (Evidence, pages 43,059–43,060).

In her report, Phillips stated that the sinus was patent or open. Phillips also indicated that she rechecked for patency before testifying for the Inquest and again found it patent. She checked for patency by inserting a small metal probe into the opening—the sinus was described as probe patent.

In his initial report for the Inquest, Taylor concluded that the suture did not close the sinus. However, when Taylor testified, he offered a different opinion:

> Of note here is a pledget suture which is placed near the coronary sinus, which is right here. And in my report I just said that it was near by, but looking at my notes from the time that I did the examination, I noted that it actually closes the coronary sinus which is right here. (Evidence, page 43,059)

Diagram 6.11 Alyssa Still – post-operative heart



Alyssa Still – pre-operative heart

1 – Subpulmonic stenosis following pericardial patch expansion of right ventricular outflow tract

2 – Suture closing coronary sinus

3 – Pulmonary artery pericardial patch

4 – Patch closure of ventricular septal defect, with probe residual leak

5 – Right ventricular outflow tract patch

Taylor also testified that, in his opinion, the closed coronary sinus was not a significant adverse factor but rather a minor factor (Evidence, page 43,075). Cornel, however, was concerned by the presence of the suture at the orifice of the coronary sinus, because it might have contributed to the failure to resuscitate following cardiac arrest (Exhibit 353, page 39B).

Contraction band necrosis

Necrosis is the death of an area of tissue and may follow a wide variety of injuries. The injury activates enzymes in the cells that destroy the damaged cells, resulting in dead or necrotic tissues. There is usually a lapse of time between the injury and the development of necrosis. Pathologists can often detect the signs that indicate this lapse of time.

Phillips recorded that microscopic examination of the heart revealed patchy subendocardial contraction band necrosis of the myocardium of both ventricles. Alyssa therefore had necrotic or dead areas of both ventricles of her heart (or myocardium). This necrosis specifically affected the subendocardial region of the heart muscle—the inner third to half of the ventricle. In addition, she had necrosis in the form of contraction bands. These microscopic structures in the heart muscle appear like bands of dead tissue and are formed by over-contraction of the muscle cells. The presence of any necrosis decreases the heart's ability to conduct electricity normally and to pump normally.

According to Phillips's testimony, there is normally a lapse of about four hours between the time of the injury and the development of contraction band necrosis.

Taylor testified that the type of necrosis that Alyssa experienced usually indicates inadequate myocardial protection during open-heart surgery, although it can also occur with cardiac arrest and with the administration of certain drugs, such as adrenalin. He said:

> In this setting the thing I would be thinking of as far as trying to put everything together would be some injury suffered as a result of unsatisfactory or insufficient myocardial protection during the long bypass procedure. (Evidence, pages 43,080–43,081)

In Taylor's opinion, the necrosis developed during surgery and was a sign that the heart had not been provided with sufficient myocardial protection. Taylor also testified that the fact that Alyssa had prolonged surgery, needed inotropic support and was acidotic were all indications that acute myocardial impairment had occurred during surgery.

Edema

The autopsy revealed widespread retention of fluid, or edema. This may be an indication that the heart's capacity to pump had been compromised. The autopsy detected:

- subcutaneous edema (of the tissues under the skin);
- pulmonary edema (of the lungs);
- cerebral edema (of the brain); and
- myocardial edema (of the heart).

Subcutaneous edema

Subcutaneous edema was particularly apparent in Alyssa's face and eyelids. This form of edema does not necessarily signify that there has been excessive damage to the child during surgery. Rather, the presence of edema here only signifies that the patient has retained a considerable amount of fluid.

Pulmonary edema

Microscopic examination of lung tissue revealed diffuse areas of congestion and patchy areas of edema fluid in the air sacs (alveoli). Pulmonary congestion occurs when the blood vessels of the lung are so filled with blood that they are distended.

Taylor testified that:

> Edema fluid in the lungs indicates that there is some left heart failure or injury to the lining of the small blood vessels in the lungs, such that blood cells can't leak out but fluid from the lung can leak out. (Evidence, page 43,078)

Taylor wrote in his report that pulmonary congestion and edema were significant adverse factors in this case (Exhibit 336, page 5.1). Pulmonary congestion and edema can develop very quickly and might have been as a result of Alyssa's cardiac arrest, rather than the cause of it.

Cerebral edema

There was also swelling or edema of the brain. Microscopic examination of the brain revealed evidence of acute hypoxic/ischemic injury or new brain damage as a result of a lack of oxygen and blood flow. Odim and Taylor differed as to the source of the damage. Odim was not surprised that there was brain damage, given the resuscitative measures undertaken. He testified that:

> It's not unusual after cardiac arrest to have lack of cerebral blood flow because the heart isn't pumping for 40 minutes. (Evidence, page 24,929)

Taylor believed that the brain damage occurred most likely during the operation:

> There is insufficient time for the changes to occur from when she arrested and died to when the autopsy was done. It had to be 12 hours or even longer before that. (Evidence, page 43,095)

The reduction in blood flow through the coronary sinus and the presence of contraction band necrosis in the heart meant that less oxygen could be delivered to the brain, leading to brain damage. The weight of the evidence suggests that both the heart and brain damage did occur during surgery.

Myocardial edema

Taylor also testified that he found mild myocardial edema. This can occur when fluid collects between the cells of the heart muscle. Taylor testified:

> I consider that a significant factor because I believe that myocardial edema in a heart that has been subjected to open heart surgery and bypass can occasionally cause problems. And I make that statement on the basis of somewhat similar cases to Alyssa that I encountered in the past, where really the only finding was myocardial edema. I think myocardial edema occurs to greater or lesser degree after heart surgery almost always. But sometimes, depending on the metabolic state of the child,

> other anatomical factors, the myocardial edema may cause the heart to become dysfunctional and put it at jeopardy for something like an arrhythmia. (Evidence, page 43,077)

Hudson did not think that myocardial damage or dysfunction caused the cardiovascular collapse:

> Poor myocardial function would likely have been evident sooner, and would be more likely to be manifest as progressive deterioration rather than a sudden, catastrophic event. Therefore, I do not feel that poor myocardial function was the primary cause of this child's death. (Exhibit 307, page 5.19)

In response to questioning about the widespread edema, Odim indicated it was a result of a variety of factors: including bypass and medication. It was not, he felt, unusual, given the circumstances (Evidence, pages 24,928–24,931). While there is truth to this, as several witnesses pointed out, events during surgery may have unnecessarily contributed to the development of this edema.

The repair to the ventricular septal defect

In his examination of Alyssa's heart for this Inquest, Taylor identified a two-millimetre leak in the Dacron patch closing the ventricular septal defect. In his testimony, he said that it was not possible to determine if the leak was caused before or after Alyssa's death.

CAUSE OF DEATH

Odim noted in the chart that "Alyssa had a bradycardia episode following coughing and ET tube suctioning which led to hypotension and cardiac arrest." (Exhibit 11, page STI 47) He found no build-up of blood around her heart when he opened her chest. Despite resuscitation, there was no cardiac activity or output. He also wrote that "The cause of death was sudden and appeared related to a vasovagal episode from ET tube suctioning. Prior to the event the child's post-operative course had been entirely smooth." (Exhibit 11, page STI 47) In short, Odim appeared to be attributing the death to a bradycardia or vasovagal episode that was triggered by the suctioning. He expanded on this point in his testimony.

> So my sense at the time was that she had coughed, coughing potentially could reflect increased pulmonary hypertension and then she was suctioned and when you suction she may have had a vagal response or stimulation response which slowed the heart down. In addition when you suction, at least during that brief period of suctioning, there is no oxygen getting in, in fact patients can be transiently low in oxygen and low oxygen can also cause slowing of the heart rate. (Evidence, page 24,918)

Other witnesses did not accept this view. Dr. Walter Duncan said that suctioning can be dangerous, but it is necessary for patients with endotracheal tubes after heart surgery. Without suctioning, he said, patients can literally drown in their own secretions. In his opinion, Alyssa Still's death could not be simply attributed to the suctioning.

> I think her pulmonary outlet was too small. I think she had probably right ventricular hypertension after surgery, and that would have limited her cardiac output. If you take a child who has got limited cardiac output, if you look at the rest of the pressure measurements here on my 1995 report, she was still an abnormal coagulation state, which either means that her coagulation factors were consumed at the time of the bypass run and hadn't yet normalized, or her liver was not being perfused adequately with blood to make new coagulation factors.

> She was also acidotic. Her pH was 7.22 which means that her cardiac output was limited. And she was using anaerobic metabolism to generate energy. Her bicarbonate was low at 14, it should be 20 at least. It came up slightly by 8:15.
>
> If you look at Dr. Giddins' note, she was fluid overloaded. Her weight prior to surgery 6.7 kilos and at autopsy it was 7.9, which means she was up 1,200 grams, which is 20 percent increase in body fluid. Now, this does not go in keeping with somebody who has had a successful event surgically. There is too many negative things happening here. So I don't think that you can simply say this was a death due to suctioning. (Evidence, pages 41,418–41,419)

Suctioning can in fact stimulate the vagus nerve, which will in turn slow the heart (or produce bradycardia) and cause the blood pressure to drop. This is termed a vasovagal response or episode. Normally such episodes are transient but last longer in some patients, who may need treatment to raise the heart rate. Kesselman testified that with a typical vasovagal episode, the heart rate drops and then picks up again. "She didn't follow that pattern. There was a—the initial stimulus, which I think was the suctioning and maybe the vagal kind of tone stimulation was involved with it, but I think there had to be more to it than that or she would have just quickly recovered." (Evidence, page 33,965) Instead, he suggested that the situation was complicated by the fact that Alyssa's heart was compromised by surgery.

One way of treating a vasovagal episode is with a drug called atropine, although the drug may take some time to work, because the heart rate is so slow. A faster way to speed up the heart is to use a pacemaker, if one is present—as was the case with Alyssa. If the pacemaker is properly connected, it should then be possible to maintain the heart rate. Odim was questioned on why the attempt to pace Alyssa had failed. He said he did not understand why pacing had failed.

> My impression was that perhaps the biochemistry was such with hypoxemia and acidosis that they couldn't pace the heart. The patient had a low heart rate for eight minutes and cardiac output in children is a function of heart rate and stroke volume, that is, with each beat you squeeze a certain amount of volume out.
>
> Kids as opposed to adults, their squeeze out is fixed so you really have to have many beats to have an adequate output and if your heart rate goes down and stays down for an appreciable period of time, the cardiac output will go down because they can't increase the amount they eject with each beat and I think that milieux, low cardiac output and acidosis mix, sometimes can make it difficult to pace. (Evidence, pages 24,919–24,920)

Kesselman testified that during this period there had been a number of cases where there was trouble with the pacing wires. Inquiries were made with the firm that manufactured the pacing equipment and the equipment itself was examined by the HSC. In the end, Kesselman said there was no satisfactory explanation of what was wrong with the pacemakers. He speculated that:

> Well, I think in this scenario where we have evidence that the heart muscle is not working very well, that it has been compromised, and evidenced I say both by her early post-operative low cardiac output, and evidenced by the slowing of her heart rate that didn't pick up as the perfusion dropped, that when the heart muscle is sick enough that it doesn't matter what stimulation you apply on those cells, if they don't have the energy, they can't respond. (Evidence, page 33,967)

In his testimony, Odim suggested that the vasovagal episode might have been prevented if Alyssa had been pre-treated with atropine. Odim also said he believed that Alyssa was treated with atropine once she suffered the vasovagal response. Kesselman could not recall any conversation regarding pre-treatment with atropine, although he said pre-treatment was not usually given at HSC. This was because the increased heart rate from the drug was not always a positive development in some patients, and atropine also had a side-effect of drying and thickening secretions, making it harder to suction them from endotracheal tubes.

In his report for this Inquest, Hudson wrote at great length on the cause of death. In his report he stated:

> I do not agree with the attending surgeon's assessment that the cause of death was due to a vasovagal episode initiated by tracheal suctioning, for two reasons. First, the decrease in heart rate began during a coughing spell prior to suctioning the endotracheal tube, thus suctioning could not have been the initial cause of the bradycardia. Second, and more important, is that a vasovagal episode would have easily responded to cardiac pacing. (Exhibit 307, page 5.19)

The evidence presented by Kesselman, Hudson, Duncan and Taylor is persuasive. Normally, a vasovagal episode would have quickly ended on its own or pacing would have brought the episode to an end. However, Alyssa's heart had been severely compromised during surgery. It therefore simply might not have been able to respond adequately to a vasovagal episode on its own, and without the assistance of the pacemaker, very quickly deteriorated. It would appear that the contributing factors to the heart's inability to respond could have been:

- lack of relief of the pulmonary stenosis;
- the suturing closed of the coronary sinus; and
- the length of surgery.

This view is supported by the presence of subcutaneous, pulmonary, cerebral and myocardial edema, as well as the autopsy finding of myocardial necrosis.

FINDINGS

As noted above this case gives rise to the following questions:

- Was Alyssa's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Alyssa healthy enough to undergo an operation?
- Were there technical problems with the operation?
- Was the PICU adequately equipped for her case?
- What was the cause of death and was it preventable?

Was Alyssa's family provided with sufficient information to allow them to give informed consent to the procedure?

It is clear from the testimony provided to this Inquest that Alyssa's family had not been told about the recent deaths in the program. Based on the evidence, it would also seem that they would not have been told about the state of dysfunction of the operative team and the inexperience of the surgeon. In fact, there is some suggestion that information was passed to Alyssa's mother as to Odim's status within the profession that would not have been accurate.

- Finding

  It is reasonable to conclude that in the circumstances of this case, a patient or parent was entitled to know the true state of affairs of the program and that the team was not enjoying good results. The evidence tends to suggest that Alyssa's family was not provided with sufficient information to allow them to give informed consent to the procedure.

Was Alyssa healthy enough to undergo an operation?

- Finding

  The evidence presented to the Inquest raised questions about the decision to take Alyssa to surgery in light of a possible infection. However, the consulting witnesses in their testimony deferred to the decision that was made by Giddins, Odim and Wong. It is difficult to conclude, therefore, that their decision was an incorrect one.

Was the PICU adequately equipped for her case?

- Finding

  The events in PICU—including the need to call Youngson at 0400 hours—indicate that Odim had not yet ensured that the Unit was able to handle his patients postoperatively. These problems persisted, despite the efforts of the PICU staff to have the Unit properly equipped. Comments made by both Kiesman and Kesselman in testimony also raise questions about Odim's approach to his colleagues.

Were there technical problems with the operation?

- Finding

  The evidence suggests that Alyssa's coronary sinus was sutured closed, that there may not have been sufficient myocardial protection and that there was not sufficient relief of Alyssa's pulmonary stenosis.

What was the cause of death and was it preventable?

If Alyssa did not have an infection, there are unanswered questions about her death. While Odim indicated that her death was due to a vasovagal incident stimulated by suctioning, witnesses to this Inquest indicated that such a problem should have responded to pacing, which it did not. This leads one to question whether Alyssa's heart had been weakened during surgery or if the repair was not adequate. In his report Cornel also noted that there might have been inadequate relief of the pulmonary valve stenosis.

The questions that were raised about the lack of relief of the pulmonary valve, the suturing of the coronary sinus, and the presence of widespread edema, myocardial necrosis, and brain damage all suggest that it was during the course of surgery that Alyssa's heart was compromised to the point that it could not respond to pacing. Witnesses have also raised important questions as to whether or not there was sufficient myocardial protection during surgery.

Unfortunately, the records do not provide an explicit answer to this question. However, the damage done to Alyssa's heart suggests that protection was not adequate. In his report Dr. Walter Duncan commented that the three hour and seven minute pump time was lengthy. As noted elsewhere in this report, lengthy pump times led to an increase in post-operative problems.

Finally there is the failure of the pacing wires to assist the child to recover from the bradycardia that developed following the coughing spell. The wires should have worked, but either they were improperly placed or the heart was so compromised as not to be able to respond appropriately.

■ Finding

The evidence, therefore, suggests that the child died from compromise to the functioning of the heart brought about by a complicated and lengthy operation, and an inability of the heart to respond to pacing. Again, it is difficult to come to a definitive statement about whether or not this death was preventable. However, the lengthy bypass time, the possibly inadequate myocardial protection and the suturing of the coronary sinus suggest that this death might have been preventable.

BORTON ASKS FOR A TRANSFER

Borton testified that she encountered Giddins on the street outside the VCHC the day after Alyssa died. Giddins asked her about a patient who was to undergo a valvotomy. Borton said that she told him that she was not able to go into the unit, because she was so distraught about Alyssa's death. Shortly after this she recalled arranging a meeting with Boyle.

> I went into her office, and I remember it distinctly because I went in and I sat down and I said to her, I just want to let you know that I have concerns about the cardiac program, and I started to cry. And she was very supportive of me, you know. I felt that she was the first person that really heard me. Dr. Giddins didn't have reservations; Lois didn't have the same feelings that I had, she didn't share that with me and I didn't—to the extent of how I felt, I felt that Isobel understood and supported me. (Evidence, page 18,197)

At that point Boyle said that she would work in helping Borton find work in another area. Before that happened, the program went into a slowdown because of the anaesthetists' decision to withdraw services. As a result, Borton remained with the program throughout the summer and early fall.

MAY 11–12—THE CASE OF FE

FE was a one-year-old child who underwent two open-heart operations in May 1994. The second operation was because of severe bleeding after the first operation.

FE was born on May 19, 1992. At birth he was diagnosed with tricuspid atresia and needed an immediate operation. He was given a right modified central systemic to pulmonary artery shunt (Blalock-Taussig) and also underwent a balloon atrial septostomy.

On December 7, 1993, a cardiac catheterization revealed severe hypoplasia of the right ventricle. Both the tricuspid and pulmonary valves were dysplastic and stenotic. There was moderate to severe tricuspid regurgitation, severe right pulmonary artery stenosis and mild mitral valve regurgitation. There was a small ventricular septal defect with a predominantly left to right shunt. The central aortic right pulmonary shunt was patent.

At the pediatric cardiac surgery conference on April 6, 1994, FE was described as cyanotic, with clubbed fingers and slow growth. It was suggested that he was a candidate for a Fontan procedure.

On May 11, Odim chose to replace FE's aortic shunt with a Glenn shunt. During this procedure, his heart was opened to allow Odim to remove the atrial septum. This ensured that blood coming back to the right atrium would have an outlet. As in a number of other operations, FE had bleeding problems. The problems were thought to be due to a coagulopathy, since they were treated with special transfusions. However, the bleeding problems were to recur.

By the early morning of the next day, FE showed signs that he could not tolerate his new shunt. His oxygen saturation was very low, and he suffered what witnesses described as a major hemorrhage from his chest tubes. Although he received a transfusion, the decision was made to re-operate. As a result, most of the surgical team was recalled and FE was taken back to the OR.

Initially a number of drugs, including nitric oxide, were used to try to increase the blood flow to his lungs. When this failed to have the desired result, Odim attempted to open up FE's narrowed pulmonary artery. When this brought no relief, Odim decided to create a new shunt in addition to the Glenn shunt.

FE was returned to the PICU in stable condition with his chest open. The sternum was closed on May 16 and he was discharged from the PICU on May 30, 1994. Several witnesses expressed concern over the amount of bleeding that FE experienced.

Swartz had earlier expressed her concern that Odim appeared often to assume that bleeding problems were due to a coagulopathy, rather than to any surgical problems. This concern had arisen in the Goyal case. However, according to her notes, this concern also arose in the FE case. When FE was taken back to the OR, she wrote:

> There appeared to be sites of bleeding and other sites were very dry, yet it was only with the assistance and insistence of the assistant surgeon that these bleeding sites were finally identified and treated appropriately. The surgeon said he couldn't really see any bleeding sites. (Exhibit 127)

The FE case also increased Feser's concerns about the amount of post-operative bleeding suffered by pediatric cardiac cases arriving in the PICU from the OR. Gary Caribou had lost 200 millilitres of blood in his first hour in PICU, while Jessica Ulimaumi had lost over 600 millilitres in her first 24 hours in the PICU. FE lost 687 millilitres in his first hour in PICU. Feser testified that in her experience, a loss of at most 20 millilitres an hour was acceptable.

In his evidence, Odim suggested that post-operative bleeding was not excessive, although it might have been higher than what the PICU staff had experienced under Duncan. Odim said that he (Odim) tended to send his patients to the ICU earlier than Duncan did. Odim admitted that he felt that patients should be transferred out of the OR and into the ICU as soon as possible, because he felt that the ICU staff was better equipped to address post-operative issues than was the operating-room staff.

THE CASE OF RM

Other people who worked at Children's Hospital were becoming aware that there were growing concerns about the Pediatric Cardiac Surgery Program. Mary Jane Wasney, a surgical nurse at Children's Hospital, had heard about the deaths of a number of children and knew that operations were taking longer than expected. This was of particular importance to her, since her nephew, RM, was scheduled for a staged Fontan procedure in June 1994 at the HSC. This was similar to the type of surgery that FE had undergone. When FE had to be taken back to the OR the day after his first operation, she became alarmed. She shared her concerns with Youngson, who advised her to speak with Borton. She went to Borton in tears, worried that her nephew was going to die. Borton testified:

> I told her that if you have reservations, you need to talk to Niels, you need to talk to Niels about your reservations about the surgery, and you can get him referred out, Niels could refer [the nephew] out of Province if it came to that. (Evidence, page 18,210)

Wasney made an appointment to see Giddins and Hawkins. She gave this account of that meeting to the Inquest:

> I said that I wouldn't be worried if things were going well. And then he said, which shocked me, was that he would be surprised if things were going too well, that there is always a learning curve in any new program.
>
> I understood that, and I said, yes, but children are dying. He said, yes, but that was unfortunate, but he was confident that Dr. Odim could do [the nephew's] surgery because he had done numerous of these types of surgeries. (Evidence, page 20,357)

Here again, one sees the concept of a learning curve being invoked to justify poor surgical outcomes. It should be remembered that at the same time that Giddins appeared to acknowledge that the team was making difficult progress along a learning curve, he was discouraging parents from having their children treated at other, larger centres.

Wasney also asked Wong, Swartz and McNeill for advice. Wong testified that he told her that:

> ... in view of all of the innuendo and all of the circumstances that were happening at that time, especially—I didn't tell her about the walkout [described in the next section of this report], but in view of the circumstances at that time, I suggested that Saskatoon might be a better place to go. (Evidence, pages 19,859–19,860)

In her testimony, Wasney recalled that all three anaesthetists she spoke with recommended against having the operation done in Winnipeg. In the end, the child was operated on in Saskatoon in June, after the Winnipeg program had reduced its scope of activity.

THE ANAESTHETISTS WITHDRAW SERVICES

MAY 16, 1994 – THE MEETING OF THE SECTION OF PEDIATRIC ANAESTHESIA

On Monday, May 16, 1994, the pediatric anaesthesia section met. It was at this meeting that the section voted to take the extraordinary step of withdrawing services to pediatric cardiac surgery. Swartz, McNeill, Wong and Reimer outlined their concerns with the program. They were concerned about morbidity and mortality, the apparent lack of monitoring and the deteriorating relations among team members. According to McNeill, the members of the section who did not give anaesthetics for open cardiac procedures all expressed their support for the four who did.

Craig was present at the meeting, although he left during the discussion. Before leaving, he indicated that he would support the section members in whatever decision they reached. At the time Craig recognized that withdrawal of services was an option under consideration.

After continued discussion, the section decided to issue a statement about cardiac anaesthesia. The statement was sent to Wiseman because he was the head of pediatric surgery. The memorandum was to inform him of a decision to suspend the provision of cardiac anaesthesia services for open cases until a review of the Pediatric Cardiac Surgery Program was undertaken. The suspension of services was to go into effect on May 17. Ullyot testified that she initially opposed the decision to withdraw services on such short notice. However, she said, the anaesthetists were adamant that the program be halted until it was determined if it was viable.

The section also selected McNeill to serve as the head of pediatric cardiac surgery anaesthesia. This appointment was not widely communicated at the time. Indeed, it was not until October 12, 1994, that Ullyot sent a memorandum to Craig, with copies to the appropriate heads and VCHC staff, announcing McNeill's appointment as director of pediatric cardiac anaesthesia.

After the meeting ended, Ullyot drafted a memorandum outlining the decision that had been taken at that day's meeting. In the evening she telephoned Craig and read the memorandum to him. Craig said he indicated that he would continue to support the anaesthetists in their action. He testified he did this because the issues they had raised were serious and it appeared that they had not been able to have them properly addressed.

THE MAY 17 MEMO FROM THE ANAESTHETISTS

On May 17, Ullyot wrote a memorandum to Wiseman informing him of the decision that the anaesthetists had made. The memorandum read as follows:

> MEMORANDUM
>
> TO: Dr. Nathan Wiseman
>
> FROM: Section of Pediatric Anesthesia
>
> DATE: 17 May 1994
>
> Re: Pediatric Cardiac Program
>
> The Section of Pediatric Anesthesia has concerns regarding the perioperative morbidity and mortality of pediatric cardiac cases at Children's Hospital.
>
> We propose an immediate review of cases to date and the implementation of a mechanism whereby the structure and function of the Pediatric Cardiac Program can be developed in a continuous manner. The process should involve surgery, cardiology, anesthesia, nursing, intensive care and perfusion personnel.
>
> We anticipate that ongoing planning and review will ensure the development of a successful program and we would participate fully in this process.
>
> At a meeting yesterday of all members, the Section of Pediatric Anesthesia unanimously agreed that pending the recommendations of the immediate review we suspend the provision of cardiac anesthesia for open cases as of Tuesday, May 17, 1994.
>
> SU/jt
>
> cc: Dr. D Craig
>
> Dr. R. Blanchard
>
> (Exhibit 19, Document 240)

McNeill testified that, in her mind, services were withdrawn in an effort to draw attention to the fact that the program was not being properly supervised. She testified that before the memorandum was issued, no one from Anaesthesia had formally approached Bishop, Giddins or Odim about their concerns about the program. McNeill testified that it was apparent to her at the time that Giddins did not share her concerns about the program, since he was continuing to refer complex cases to Odim. She said she did not speak to Odim because she had found it difficult to speak with him, particularly as the relations between the surgeon and the anaesthetists had deteriorated.

> In retrospect, I regret that I didn't speak to Dr. Odim just on a personal level, that I didn't speak to him. But I also, in retrospect and having knowledge now that I didn't at the time, I think that my assessment of how he would have taken my remarks was accurate. I don't think that it would have been constructive. (Evidence, page 13,237)

When asked why the anaesthetists felt it was necessary to take this extraordinary step, McNeill said:

> Well, I guess we didn't have confidence that there was an active process in place that was monitoring the program. There was, the program was functioning, I mean, there was cases booked for the next week. I don't remember what they were, but we came to the point where we felt that we didn't have confidence in the program and we didn't want to wait any more time and possibly have more negative outcomes. (Evidence, page 13,242)

When asked why the May 17 memorandum did not make specific mention of concerns with Odim, McNeill testified that the anaesthetists felt that to focus on the surgeon would draw attention away from the issue of proper program management.

This was an extraordinary step to have taken. One might wish to take issue with the anaesthetists taking such a unilateral action without providing more warning or lead time. Certainly the department heads who were affected by this withdrawal expressed frustration on this point. Also, it might have been appropriate to have made further approaches to Giddins, Wiseman and Odim before taking such precipitous action, particularly since operations were scheduled for that week. Finally, when the action was taken, it might have been more appropriate to have sent the memorandum directly to Blanchard and Bishop.

These things being said, it is also apparent from the evidence that the anaesthetists had real reason to be concerned. It is also apparent that they had attempted to use a variety of informal channels and had met with no progress.

Some witnesses suggested that the anaesthetists and nurses should have raised their concerns at the CVT conferences. The evidence establishes that whenever a case was presented to the CVT conference in 1994, invariably Odim would undertake to perform the operation, rather than referring any case out of province. Giddins felt that the question of whether or not a case should be referred out of province was one that the surgeon should make, and he did not make any out-of-province referrals on his own. Giddins testified that he could recall only one instance where Odim declined to perform a surgical procedure. That one exception was a child who had initially undergone surgery in Toronto. In that case, the child was returned to Toronto for follow-up surgery.

Once Giddins and Odim had discussed the need for surgery, the patient would be scheduled for an operation at a forthcoming date. Then the case would be discussed by all members of the OR team at the preoperative conference.

Giddins said he felt that it was at these meetings that any concerns about proceeding to surgery could be raised by other members of the team. Yet these other members indicated that they felt that by the time these meetings were held, the decision to proceed to surgery had already been made by the cardiologist and surgeon. In addition, the matter had already been discussed with the family. In other words, they felt that the decision to operate was a *fait accompli*. That being the case, they felt there was little opportunity for them to discuss any concerns or raise any objections they might have to a particular patient going to the OR the following week. The only exception would be if there was an issue specific to their field of specialty that had not been earlier considered.

Borton testified that before mid-May 1994 she never heard any discussion at a pre-operative conference of the possibility of sending a child out of province for surgery. In her testimony, Fleming said that she had attended the pre-operative conferences for children whom she was likely to be caring for in the PICU. She testified that by the time a patient was discussed at the pre-operative conference, a decision had already been made to go forward with surgery.

THE DISTRIBUTION OF THE MEMO

Ullyot said that she sent the memorandum to Wiseman because he was the head of the Pediatric Operating Room Committee and the head of pediatric surgery. She saw the matter as a pediatric concern, rather than a surgical concern.

She said she did not send a copy to Odim because she wanted to give a message that the anaesthetists did not see the surgeon as the sole problem. She testified that following the meeting that took place on the morning of May 17, she felt that she should have sent copies of the memorandum to Giddins and Odim. She said that she did not even consider sending a copy of the memorandum to Unruh and was unaware of his responsibility for Odim at the time, as section head of CVT surgery.

Copies of the memorandum were sent to Craig and Blanchard. Wiseman testified that, in his opinion, the memorandum should have been sent to Blanchard, with only a copy going to him. However, Wiseman testified that he never received a copy of the memorandum in his office.

Blanchard also said he did not receive or get the memo. He said that when he arrived at his office on the morning of May 17, his secretary told him the memo had been delivered. When he looked for it a short while later, he was unable to find it.

BISHOP IS NOTIFIED

Ullyot testified that on the morning of May 17 she telephoned Bishop to inform her of the decision. Bishop testified that she could not recall the phone call, but she did receive a copy of the memorandum that morning. After reading the memorandum, Bishop quickly arranged a meeting in her department for later that morning. Bishop also telephoned Odim and Giddins. Neither had heard of the memorandum and agreed to attend a meeting in her office. At the time of the withdrawal by the anaesthetists, a patient was scheduled for later that week.

Bishop testified that she was angered by the fact that the service was being shut down without any advance notice. She said that this made it very hard to provide patients with options. She was also surprised to learn that the anaesthetists had not fully communicated their concerns to Odim and Giddins.

Blanchard testified that he was astounded by the withdrawal of services.

> It seemed to me that if you have this kind of clinical problem, and there was substance to it, and we had no idea whether there was substance to this, why hadn't that been sorted out between the anaesthetists and the surgeon and the cardiologist. (Evidence, page 36,505)

He also testified that it appeared to him that, aside from possible problems with mortality and morbidity, there were serious problems with communication and interpersonal relationships. He said the team that had been in place had unravelled. When asked if the team had actually existed in the first place, he responded:

> Well, it existed. I mean, the system was there, but the functioning seemed to not be there. (Evidence, page 36,508)

He was only beginning to appreciate the seriousness of the situation.

Chapter 7

THE SLOWDOWN

MAY 17 TO SEPTEMBER 1994

The anaesthetists' memorandum of May 17 led to an immediate slowdown in the Health Sciences Centre Pediatric Cardiac Surgery program. Initially, only low-risk cases were done. The slowdown lasted until the end of July, when medium-risk cases were permitted, and in September of 1994 the program returned to doing high-risk cases. The slowdown should have given the HSC administration an opportunity to identify and address the shortcomings that surrounded the program's restart in February 1994. However, as the events outlined in this chapter indicate, that did not happen. As a result, the program experienced another half-year of turmoil and tragedy before it was completely suspended.

On May 17 and May 18, the HSC departmental leadership responded to the anaesthetists' withdrawal of services. These two days were among the most crucial days in the history of the program. Decisions made at that time led to the creation of what became known in the hospital as the Wiseman Committee. That committee was supposedly mandated to address the problems raised by the anaesthetists' action. It met throughout the summer of 1994 and it was on the recommendation of this committee that the Pediatric Cardiac Surgery Program returned to full capacity in September 1994. This chapter reviews the operations that were undertaken from May 17 to early September. Special attention is paid to the deaths of two children. In addition, this chapter examines the creation and functioning of the Wiseman Committee during this period.

THE MEETING IN BISHOP'S OFFICE

On the morning of May 17, on arriving at her office, Dr. Agnes Bishop, the head of the pediatrics department, was told that the pediatric anaesthetists had withdrawn their services from the Pediatric Cardiac Surgery Program. Given the assurances she had only recently received from Dr. Nathan Wiseman, that the issues being raised about the program were not shared by all the anaesthetists, she was understandably surprised and even angry.

In early May, it will be recalled, Bishop had asked Wiseman to gather information about complaints that had been made to her about the program. She had spoken to Isobel Boyle, the director of pediatrics and child health nursing, about the concerns of the nurses and to Dr. Suzanne Ullyot about the anaesthetists' concerns. Ullyot had told her that the anaesthetists had agreed to establish a liaison with Dr. Jonah Odim and Dr. Niels Giddins. Yet, when Bishop called Odim and Giddins that morning, she was informed that neither had been approached by the anaesthetists about their concerns with the program. It was obvious to Bishop that the team was communicating at an extremely poor level.

Her immediate concern on learning about the anaesthetists' withdrawal was for the patients who were scheduled for cardiac surgery that day and later in the week. If those patients could not be operated on in Winnipeg, arrangements would have to be made to offer their families options, including the possibility of deferring the procedure or transporting the child to another facility. In addition, to prevent the spread of rumours, she wanted to ensure that the HSC gave all parents a coherent explanation of why cases were being delayed.

Bishop called Dr. Doug Craig, head of the Department of Anaesthesia, Dr. Robert Blanchard, head of the Department of Surgery, Ullyot, Odim, Giddins and Wiseman to attend a meeting in her office that morning. She did not invite Boyle, nor any of the nurses involved in the program, because in her view, the meeting was meant to deal with the medical implications of the anaesthetists' action. Dr. Ann McNeill also attended the meeting, at Ullyot's invitation.

At the outset of the meeting, Bishop expressed her dismay at the withdrawal of services and the fact that it had been undertaken on such short notice. In response, McNeill and Ullyot explained that the anaesthetists had become concerned over the fact that deaths in the program were apparently not being systematically reviewed, and that the anaesthetists were not confident that events within the program were going to be reviewed.

However, they did not voice their concern over the ability of the pediatric cardiac surgery team and, in particular, the surgeon, to perform the operations that the program was undertaking. When asked to explain during her testimony why the anaesthetists were hesitant to state that concern explicitly, McNeill said they were not certain that they were qualified to pass judgment on Odim's skills and abilities, but they wanted someone to do so. She explained that she was particularly hesitant to criticize Odim since she was not a surgeon. She felt, however, that if a review was undertaken, any surgical problems would be identified and would lead to an appropriate resolution.

During the meeting, it was revealed that the anaesthetists had not spoken with either Odim or Giddins about their concerns. Giddins testified that, aside from the comments made to him earlier by Joan Borton and Wiseman, this was the first time he had been made aware of the anaesthetists' concerns with morbidity and mortality.

Craig wondered if his assumption that there were appropriate lines of communication between the pediatric cardiac anaesthetists and Odim had been correct. It was becoming apparent to him that there had been little, if any, communication between the anaesthetists and Odim and Giddins about the anaesthetists' concerns. However, at the meeting Craig kept those concerns to himself. Both McNeill and Ullyot felt that Craig was supportive of the anaesthetists' actions at the meeting.

Both Blanchard and Bishop expressed their concern that they had not been made aware of the extent of the concerns held by some members of the program. When McNeill expressed the view that the anaesthetists were concerned about deaths in the program, Blanchard asked, perhaps facetiously, if the anaesthetists had thought that there would be none.

Odim testified he was shocked by the decision to withdraw services. While there had been some operating-room friction to that point, he put it down to personality differences. He indicated in his evidence that he too had been concerned about the deaths:

> It was of some concern that we certainly had some bad luck, had some tough cases, and had some children that we didn't anticipate would die who died in the post-op period. And obviously those were concerns. And all along I was formulating ways in which we could help and improve the situation both from the surgical point of view, from the pre-surgical point of view and post surgical point of view in terms of developing a more efficient team. (Evidence, pages 25,027–25,028)

He testified that he had tried to encourage members of the team to attend post-operative Morbidity and Mortality Rounds, where individual cases would be reviewed, but there had been a significant lack of attendance at those sessions. He felt that the members of the team had been given several opportunities to bring their concerns about individual cases to his attention, as well as to that of other members of the team, at the pre-operative conferences. He said he was frustrated by the other team members' lack of co-operation.

However, at the meeting Odim also kept those opinions to himself. He did so because he felt himself to be "on the hot seat" at the meeting and did not take part in the discussion. It is interesting that he would see himself as the centre of attention, given the lack of specific comments directed at or about him by the anaesthetists, who themselves felt that they were under the gun to justify what they had done.

It is also noteworthy that, despite the fact that Odim seemed to think that the anaesthetists were targeting him, he refused to read the memo they had circulated to Wiseman and others following their May 16 meeting. Odim testified that he did not read the memorandum until just before appearing for this Inquest. It is difficult to understand why he would not have read the memorandum earlier. This fact does not speak well of him.

THE DECISION TO CONDUCT A REVIEW

It was apparent to all at the meeting that the program was in serious trouble. As a result, a decision was made to create a review committee. This was known as the Pediatric Cardiac Review Team, or the Wiseman Committee, since it was chaired by Wiseman. The committee held its first meeting on May 18. In his testimony, Craig noted that in all his years in health care he had never seen a major problem addressed as quickly as this problem was. In retrospect, however, the committee may have been struck too hastily, as some important matters were not addressed.

The written direction given to the committee was to "deal with on-going issues related to the Pediatric Cardiac Surgery program in an effort to best serve the needs of the pediatric patient." (Exhibit 20, Document 278 B) It was understood that the committee would review the cases that had been performed to that point in the program, and would also work to address the concerns of team members. What was not clear was how and when the committee was to report back, and to whom it was to report.

The decision to establish the committee precluded referring the matter to at least two existing bodies: the Pediatric Operating Room Committee and the Children's Hospital Management Advisory Committee. These bodies were described in Chapter Four of this report. This decision was not unreasonable. The personnel on the Wiseman Committee had more direct knowledge of the issues under discussion than did the members of the Pediatric Operating Room Committee, while the Children's Hospital Management Advisory Committee was a product of the mid-year reorganization of the HSC. Its membership would not have had direct knowledge of events in the program; nor would they have had expertise in the field.

However, because the committee was created outside existing processes, it lacked a clear structure and rules of procedure. It was not clear what authority the committee had to change existing procedures or seek advice from outside experts.

WHAT TO DO ABOUT THE EXISTING CASES?

There remained the question about what to do about the cases that had been scheduled for surgery. In taking the action they had, the anaesthetists had forced the delay or transfer of potentially all open-heart pediatric cardiac surgical cases that would normally have been done at the Children's Hospital. Once the review had been agreed to, Bishop and others broached the question of performing some operations while the review was being undertaken.

Giddins and Odim (among others) supported the view that low-risk open-heart operations could still be performed during the review. McNeill testified that originally the anaesthetists had wanted a moratorium on all open-heart cases, including low-risk cases. Following the creation of the Wiseman Committee, she testified that "we left with having agreed that we would not withdraw entirely, and you know, that we would set up a review process to address things that were going on in the program." (Evidence, page 13,262) Since a review of the program had been set in place, the anaesthetists felt that it was impossible for them to refuse to participate in all open-heart operations. However, they maintained their concern about the degree of complexity of the cases that were being considered or undertaken. At the meeting, McNeill and Ullyot agreed that the anaesthetists would participate in less-complex, low-risk open-heart cases but that they would not participate in cases of higher risk until the review was complete.

INFORMING HSC SENIOR MANAGEMENT

None of the three department heads at the meeting reported on the withdrawal of services to Dr. Ian Sutherland, the vice-president to whom each of them reported. Blanchard testified that this was not the result of a conscious decision and acknowledged that it should have been done, if for no other reason than out of courtesy.

Craig testified that "telling the vice-presidents about something like this, you know, they should know, but it's not really that relevant to solving it on the clinical side. At some point we would need the vice-presidents' involvement and support, but it's not going to help solve an issue right today, of this type." (Evidence, pages 34,506–34,507)

Bishop testified that while she did not brief Sutherland on the issue, she did speak with her new vice-president, Helen Wright, about the developments in the program. Bishop was not sure when that took place. Under the reorganization that took place on June 1, 1994, the Department of Pediatrics and Child Health began to report to Wright. However, until the time that she left the HSC, Bishop's superior was not Wright but Sutherland. Wright testified that she was informed of the existence and working of the Wiseman Committee, but not of the anaesthetists' withdrawal of services.

The issue was also not raised at the meeting of the Medical Advisory Committee of the hospital that was held in June 1994. This committee was the senior patient-care committee responsible for advising the HSC board on all matters concerning medical policy and issues. Blanchard, Craig and Bishop were all members of the committee. The events in the program certainly fell within its mandate. Throughout all of 1994, however, the committee was never informed of the problems within the program.

MEMBERSHIP ON THE WISEMAN COMMITTEE

The pediatric cardiac review team was to be chaired by Wiseman. It was to comprise McNeill, Odim, Giddins, Dr. Murray Kesselman from the PICU, and Michael Maas, the senior perfusionist. A recommendation from Ullyot that the review team include nurses was accepted. Carol Youngson, in her position as the senior cardiac operating-room nurse, was asked to be on the committee. It appears that there was no consultation with Boyle as to how nursing should be represented. Nor were nurses themselves asked about how they wished to be involved, and they had no input into the selection of their representative.

Wiseman was chosen to head the team both because of his position as head of pediatric surgical services and his experience and knowledge of the people involved. Bishop said she supported Wiseman as the head of the committee because he was the head of pediatric surgery, was not personally involved with the program and was seen as someone with whom all the main actors could work.

It was never made clear if the members sat on the review committee as individuals or if they were responsible to a larger constituency. Certainly, none were ever selected by any constituency since, except for Youngson, they were selected at the initial meeting without reference back to any constituency. When members could not attend meetings, they often arranged to be replaced by someone from their employment area: a nurse substituted for Youngson, an anaesthetist for McNeill and a perfusionist for Maas. This suggests there was a sense that the members were in some way representative of a broader community. However, some communities were not represented at all, while others, such as nursing, were under-represented.

There was no one, either a doctor or a nurse, on the team from the neonatal intensive care unit. It was only after the committee began to consider relieving the NICU of its responsibility for treating neonatal cardiac surgery patients post-operatively that the head of the NICU, Dr. Molly Seshia, was invited to sit on the committee.

Youngson was the only nurse on the committee. As a member of the operating-room nursing unit, her selection meant that nurses from the PICU, the NICU and the VCHC had no direct representation. Youngson, in her evidence, acknowledged that she had little direct contact with her colleagues in those other units, and that she was unclear about exactly whom she represented.

In her testimony, nurse Joan Borton said that she and Lois Hawkins spoke with Giddins about the possibility of one of them being on the committee. Borton said they were told that there was no reason for them to be members. In her testimony, Feser noted that the PICU nurses were not consulted about the creation of the committee; nor did it consult them during its existence.

> There was never any requests to our unit from a nursing perspective to have any insight on what was going on, or what our thoughts were on the whole program. (Evidence, page 29,986)

Everyone involved in the Pediatric Cardiac Surgery Program endorsed the importance of teamwork. However, the actions of the program's leadership make it clear that they believed that some team players were more important than others. Nurses were no longer being told to 'see and be silent,' but their input was not actively sought. By failing to have representation from the PICU, the NICU and the VCHC nurses, the committee was cut off from important sources of information.

Finally, the team membership was deficient in that it included no outside source of pediatric cardiac surgical expertise. There was no one who could, as McNeill had anticipated, be in a position to state whether or not any of the deaths arose from surgical shortcomings. This would have required that outside expertise be on the committee.

ASSESSING THE PROBLEMS

Wiseman made notes of the May 17 meeting. These notes served as the basis for the committee's approach to reviewing the Pediatric Cardiac Surgery Program. These notes were not minutes as much as a summary of issues, and reflected Wiseman's assessment of the issues. According to the notes, the following points were discussed.

1. Program results to date (Morbidity and Mortality).
2. Need for a format for program members to vent their concerns and to discuss issues relevant to the program's success.
3. The setting for post-operative care of all patients.
4. The need to relate outcome data to the complexity of the anomaly.
5. The need for the whole team to be able to share in the grief and disappointment which results from an unsatisfactory outcome.
6. The need to recognize that interpersonal differences exist and should not be allowed to affect the program.
7. The need to improve communication in a variety of ways.
8. The need to have a baseline with respect to realistic expectations in the management of specific problems, especially in regards to more complex anomalies.
9. Finally, it was recognized that there is a need to establish a "Pediatric Cardiac Program Team". (Exhibit 20, Document 278 B)

There are a number of comments that need to be made about the list that Wiseman created following the meeting.

First of all, besides the initial mention of morbidity and mortality, several of the points on the list suggest that the problem that needed to be addressed was the unwillingness of members of the team to accept the fact that some children in the program were going to die. Points 4, 5 and 8 all reflected this assumption. These points suggested that it was necessary to give team members a realistic baseline that would remind them that some children who underwent high-risk surgery would die.

Secondly, some points suggested that some team members needed special assistance in coming to terms with these tragic results. Points 6 and 7 suggested that some team members had allowed themselves to become enmeshed in personality conflicts and had lost sight of the program's overall goals. Through improved communication and by overcoming personal animus, this problem could be resolved. Point 2, with its stress on the need for a forum where team members could vent their concerns, also reflected this analysis.

Point 1 is simply cryptic: it spoke to the need to review the surgical outcomes, but it did not speak to who should have conducted such a review or what the existing concerns about those results were. The failing on this score is particularly dramatic when one considers the conclusions the College of Physicians and Surgeons of Manitoba's Paediatric Death Review Committee reached when it finally reviewed the five deaths that had taken place in the program to this point. The PDRC, which included Wiseman as a member, concluded that two of the five deaths that occurred by the time the anaesthetists withdrew their services were possibly preventable. The Wiseman Committee, however, came to no such conclusion.

Point 3 apparently spoke to the belief that post-operative care should be consolidated. However, it did not hint at the problems that the PICU and the NICU staff had with post-operative care.

In short, the notes reflected a view that there was nothing particularly wrong with the surgical outcomes. Rather, they suggest that a number of members of the team were seen to have unrealistic expectations and were unable to cope with the deaths of five children. As a result, they focused their hostility on the surgeon.

Not surprisingly, this analysis reflects many of the conclusions that Wiseman had earlier reached in his discussion with members of the surgical team before May 17.

Thus, the review would not have any external input and would not examine questions of surgical competence because it appears Wiseman had concluded that competence was not an issue. This meant that the committee would not address the very question that had led to its establishment in the first place.

WERE THE ANAESTHETISTS JUSTIFIED IN THEIR ACTION?

In declining to provide service to the program, the anaesthetists made it clear that one of their major concerns was that there did not appear to be any monitoring of surgical outcomes. It is legitimate to ask if they were correct in this perception.

There were M & M Rounds, where cases were reviewed, particularly those that ended with the death of the patient. However, as outlined in the previous chapter, these rounds had not proven to be effective forums for an overall monitoring of results.

If one asks "were those persons to whom Odim reported monitoring his surgical results?" the answer would have to be "No." No single person ever testified to this Inquest that he or she believed himself or herself to be responsible for monitoring the results of Odim's operations. Giddins said it was not his job to do so, Unruh said it was not his responsibility, Wiseman said it was not his, and Blanchard said he thought Giddins was doing it. Yet each of these persons had some responsibility to do so. The fact that they did not perceive themselves as having this responsibility was clearly reflected in the fact that none of them was expressing any concern about results by May 17, and also in the fact that no one else saw them taking steps to address what were seen as poor results.

The question can be asked in yet another fashion: "Were there events that should have been detected and addressed as the result of vigilant monitoring?" The answer, based on the testimony presented to this Inquest, suggests that there were several disturbing events that took place in the Pediatric Cardiac Surgery Program between February 14 and May 17 that a quality assurance program should have identified.

Five children died during this period. While fatalities are to be expected in this sort of program, the circumstances that surrounded the deaths of those children clearly suggested that problems in the way the program was being run, procedures performed, and decisions made, might have contributed to those deaths.

As noted in the previous chapter, Dr. Christian Soder indicated in his report for this Inquest that "**[T]he skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations.**" (Boldface in original) (Exhibit 345, page 8) Soder wrote that surgical factors were prime determinants of death in four of the first five deaths in the program. These factors included lengthy bypass times, the need to redo surgical repairs, the failure of repairs, problems with decannulation and excessive bleeding. These were issues that any quality assurance program could have detected.

There was also evidence from the operating nurses, the PICU nurses and the NICU nurses on the lack of planning, both for the restart of the program and for individual procedures. In addition, there is evidence that Odim did not understand a number of important HSC protocols—nor did he abide by them once they had been brought to his attention.

Before May 17, nurses and anaesthetists had concluded that speaking to Odim was futile. Those who had spoken with Giddins had perceived that he felt that there was no problem. Those who spoke to Wiseman had concluded that he also seemed to feel there was no need to be concerned about surgical results. While Bishop had asked Wiseman for information after Boyle and Ullyot had spoken with her, she had received information from Wiseman that suggested the problem lay with the complainants and not with the surgeon. While Bishop had asked Wiseman for more information, it was not apparent to either the nurses or the anaesthetists that she was doing anything about their concerns.

These events led the anaesthetists to conclude that the program was not being properly monitored. They decided that they were unable to provide services to the program because they felt that it might not have been providing an appropriate level of service and was not being properly monitored. This conclusion justified them in taking the action that they did.

The question of medical ethics is always a murky field to enter, and there are relatively few absolutes. However, something that comes closest to being absolute is the obligation of a doctor not to engage in conduct that he or she feels would be detrimental or dangerous to a patient. The anaesthetists had legitimate questions about the program and those questions had been put to people whom they perceived to be in positions of authority for the program—and their concerns were not being addressed. While they could have spoken with Giddins and Odim about their concerns, it was clear that Giddins did not agree with them, and that he, as well as Odim, were perceived as being part of the problem. The anaesthetists saw Giddins's workload as preventing him from paying appropriate attention to the monitoring that the program needed. The anaesthetists felt that there were questions of surgical competence that could not be addressed directly with the surgeon involved. All of this apparently caused them to conclude that the program might be doing more harm than good to patients, and that in order to address that concern, a review was needed. The only way they felt they had to bring the matter to a head was to address the issue as they did.

OPTIONS NOT TAKEN

What was clearly needed in May 1994 was an external review of the program, one that would be conducted by people who could assess the professional competence of all team members, as well as the team itself.

Soon after the program's problems began to appear, Odim and Giddins ought to have consulted with their department heads and put a proper review in place. That they failed to do so reflects poorly on their judgment.

By way of comparison, one can look at the evidence of two of the consulting witnesses who appeared before this Inquest. Dr. Gary Cornel and Dr. Walter Duncan were both active in the pediatric cardiac surgery program at the Children's Hospital of Eastern Ontario in Ottawa. Cornel is a surgeon there, while Duncan, for a time, was its senior pediatric cardiologist.

In Ottawa in 1992, six children died of what appeared to be respiratory failure after surgery. Cornel said that he found this to be a disturbing cluster of deaths. As a result, he consulted a coroner and slowed the program down to what he called a virtual stop. A review of the program was then carried out.

> The review consisted of going over in detail everything about those cases with the pathologist, and trying to find common threads. In addition, we asked Dr. Bob Freedom from the Hospital for Sick Children to come and review the cases independently. And we asked him, especially because he is, as well as being a pediatric cardiologist, is recognized as a cardiac pathologist. So he was uniquely qualified to review the cases.
>
> Having done the review and so on, we really didn't find any real common cause. The organisms involved were different, but pneumonia and infection was an important part of these cases. (Evidence, page 44,662)

Cornel said, that while no specific cause of the problem was ever identified, the review led to a number of changes and the problem did not recur. Once the review was completed, the program was restarted slowly, with the team restricting itself initially to what Cornel described as simple cases.

On May 17, when Bishop and Blanchard became aware of the anaesthetists' withdrawal of services, they also became aware of their concerns about morbidity, mortality and the apparent lack of monitoring within the program. From that time onward, Bishop and Blanchard had an obligation to ensure that the very serious issues of competence and patient safety, which such an extreme step as a withdrawal of anaesthetic services implies, were investigated fully.

Instead, they opted for what amounted to a debriefing and team building exercise. The process put in place after May 17, 1994, was intended to appease the anaesthetists, while getting the program back in operation as soon as possible.

BLANCHARD SPEAKS WITH ODIM

After the May 17 meeting had ended, Blanchard spoke with Odim, who he feared might have been emotionally destroyed by the events. Blanchard also feared that Odim might resign on the spot. Blanchard was surprised to hear that Odim himself had concerns about the program.

> And that's when he shared with me that he did not feel supported by anaesthesia. I hadn't heard that until then. Maybe I should have, but I hadn't. (Evidence, page 36,510)

Despite the magnitude of the concerns raised by the anaesthetists, Blanchard did not discuss morbidity and mortality issues with Odim at that point.

> Well, I was trying to pick him up off the floor. I didn't see any point. We already had a process in place to deal with that. A, I didn't want to interfere with it, and B, I was trying to be some kind of support for the man. (Evidence, page 36,510)

Blanchard declined to get too directly involved in assessing the situation for himself. He did not consider going into the operating room with Odim at this or at any other point in 1994. At the same time, he obviously expected the issues to be resolved by the review team established at the May 17 meeting.

THE ISSUE OF COMMITTEE RECORDS

It is worthwhile noting that while there are documents that are referred to as minutes for many of the Wiseman Committee meetings, these are not true minutes in the sense of an officially agreed upon record of events. Ullyot testified that the minutes often came out late, or not at all, and were not reviewed at the next meeting by the committee members. Wiseman, who usually kept the minutes, acknowledged that they were really his dictated notes from the meetings and were not intended to be minutes. He acknowledged that he also did not make notes for each of the meetings, that he often wrote them some time after a meeting had been held and that occasionally they might not have been circulated in a timely manner.

He also said that the meetings were conducted with a view to seeing if a consensus would develop on each of the issues that were being discussed. Ullyot, McNeill and others said that they were of the view that the question of when or if a consensus had been reached was not one into which members of the committee had any input and that Wiseman himself seemed to be the sole judge of that. The very spottiness of the committee records underlines its lack of rigour in this area. The following discussion of the activities of the Wiseman Committee is therefore limited by the lack of a detailed record.

THE FIRST MEETING

All the committee members attended the first meeting on May 18, including Ullyot, who had become an additional member. Wiseman proposed the following terms of reference for the committee:

> The team is to maintain an on-going review of the progress of the Cardiac Surgery Program with respect to quality of care, review of results, and to foster a spirit of comradery [sic] and good inter-personal team relationships in an effort to best serve the pediatric cardiac surgery patient. (Exhibit 19, Document 241)

The committee undertook to review all open-heart procedures that had been carried out from the beginning of the reactivation of the program in February 1994. Members were asked to prepare a written list of items that they felt needed to be reviewed and that were "relevant to their own area of participation." The committee agreed that:

> The review items will be compiled and a case review will be carried out by the team, specifically looking for areas where problems may have been encountered in the past and to attempt to answer these problems in an equitable manner which is to be generally agreed upon by the team members. (Exhibit 19, Document 241)

Members were also asked to list problem areas so that the operating-room team's functioning could be improved. They were asked to produce a list of problems to be "discussed in an open format in an effort to resolve any and all issues that may have come up in the past. This is to be done in an effort to build a solid and unified team with a common goal." (Exhibit 19, Document 241)

Ullyot testified that she found it difficult to distinguish between the two sorts of issues on which Wiseman was requesting information, namely those areas that related to people's own area of participation and those areas where team functioning could be improved. This uneasy balance between areas of individual expertise and joint concern was to be a continuing stumbling block to the committee's work.

After considerable discussion, it was decided that for the coming six weeks, cases of a more complex/high-risk nature would be deferred. Patients who could not be deferred were to be transferred and, in particular, all babies with neonatal anomalies presenting as emergencies were to be referred to Saskatoon. Ullyot testified, however, that despite Wiseman's notes from the meeting, she did not believe the committee members had agreed that the hiatus would be limited to six weeks.

The May 18 meeting also laid out the ground rules for the committee's work. A number of the participants who testified had concerns about the limits on debate that emerged during the review.

One of the issues related to the instruction issued by Wiseman that committee members come up with issues to be reviewed from their own area of participation. McNeill said she felt that this instruction came from a desire to reduce tensions.

> At this point in time, there was a lot of tension, there was a lot of prickly feelings amongst, particularly between surgery and anaesthesia, okay, nursing and surgery as well, less so perfusion and other people.
>
> There was a great deal of emphasis put on the issue of communication. Communication being a major part of the problem, and if we can, you know, as they say, foster a spirit of camaraderie, that that would go along way to improving outcomes for the program.

> So, the meeting, initially the meetings were I think all people, Dr. Wiseman set the tone, but most of us were aware that there were prickly feelings, if you will, and not to be confrontational, that that may not be very constructive to be confrontational.
>
> And so I think that part of this comes from, I am trying to get at that this comes from that as a background, that people were encouraged to talk about what they were the expert in and not to necessarily comment on things outside their area of expertise, for the obvious reason, that they may be mistaken or that there wasn't a sort of a third hand, a third person corroborating or being able to validate their critique or their concerns. There was—so, that's where that I think comes from, that was my understanding of where that came from. (Evidence, pages 13,267–13,268)

McNeill said she also believed that the committee would also look at broader issues, but that this would be done in a general fashion.

> What I am saying is that rather than coming in and saying on such and such a day you did such and such, and I don't think it was right, coming into the committee and talking about the issue of inadequate pump flows in two or three cases, or of post-operative bleeding in two or three cases. To bring an issue that had applicability across more than one case, and with the view to finding a response to that problem that would then benefit all the other patients in the program, coming to the program. (Evidence, page 13,269)

The decision requiring participants to comment on issues only within their area of expertise would place some restrictions on potential conflict at committee meetings—although the meetings were far from being conflict-free. However, it also meant that significant issues of concern to many members of the surgical team would go unaddressed. As will be seen, some committee members raised specific events that touched on areas outside their field of expertise but had alarmed or disturbed them. These persons had no independent means of validating their concerns and were given discouraging responses.

The committee's decision-making process was also flawed. The minutes of the meeting contain one statement about the process by which the committee would go about its work.

> It was recommended that individual issues be dealt with so as to reach a consensus with all members of the team participating. It is proposed that specific principles of inter-team relationships would best be developed with this overall approach. It was recognized that there are many variables involved in the overall and complex issues to be dealt with however a uniform approach would help to clarify issues and make individuals better aware of expectations. (Exhibit 19, Document 241)

When McNeill was asked to explain what she understood by this paragraph, she said, "I don't understand a lot of what you just read, like what that means actually." (Evidence, page 13,277) She is correct: it is impossible to determine what sort of decision-making process that statement was proposing. McNeill said she believed that the committee was committed to consensus, as opposed to holding votes on each issue. However, there was no formal agreement or description of how consensus was to be reached. Consensus is not always a virtue, and in some circumstances it is impossible to achieve. If it is used to paper over deep division, it is not only not constructive, but can be destructive, fostering hypocrisy rather than honesty.

The focus on team building in the committee's terms of reference also made it almost impossible to address issues of competence. The review of the quality of care in the program obviously needed to be undertaken in a professional, non-vindictive fashion. However, given the strength of feeling that most of the people brought to the committee, it is easy to see that a discussion of members' concerns might, in the short-term, undermine, rather than enhance, interpersonal relationships.

Following the two-month period during which the anaesthetists and nurses had consistently expressed their concerns about the program's results to those people whom they believed to be responsible for the program, the decision of four experienced anaesthetists to withdraw services should have set off alarm bells in the offices of the HSC department heads concerned with the program. Ullyot had made it very clear in her meeting with Wiseman that the anaesthetists were concerned about deaths.

It is unfortunate that the anaesthetists had not felt able to take their concerns directly to Giddins and Odim before issuing their May 17 memorandum. It is also unfortunate that they had felt compelled to call for an immediate withdrawal of services—although in light of their serious concerns for patient safety, there was merit to that decision.

The anaesthetists had been justified in withdrawing their services. They had been faced with an ethical dilemma: they were expected to provide services to a program, yet they also had an overriding responsibility to the patients who were treated by that program. The questions they raised were valid. However, the process that was put in place could not address the questions that they raised—indeed, they felt constrained from even voicing those concerns in the committee.

Suggesting that a surgeon lacked the skills and experience to perform a particular procedure could hardly be called comradely; nor was it likely to be seen as an exercise in team building. Their withdrawal of services was an act of collective courage. Unfortunately, it did not lead to the kind of review that was required.

PREPARING FOR THE PROCESS

NURSING CONCERNS

On May 19, 1994, the OR nurses met to prepare their list of concerns for the committee. Present were Carol Youngson, Carol McGilton, Celine Weber, Susan Scott, Beatrice Zulak and Irene Hinam.

It is to be noted that nurses from the PICU, the NICU and the VCHC did not participate in this process. Given the manner in which the committee was structured, it is understandable that the operating-room nurses did not include nurses from other units in this process.

The nurses prepared a two-page list of nursing concerns, which was submitted to the committee. They broke these concerns down into three categories: communication, morale and confusion regarding roles.

Communication

Under the heading of communication, the nurses spoke of how they had attempted to arrange a meeting with Odim before the first operation to discuss the equipment he would need. They said that Odim left them with the impression that he was familiar with the equipment they had in stock and would work with the existing equipment. After examining documents Odim had given them that described specific surgical procedures, the nurses had concluded that except for a number of special sutures (which they had placed on order), they had the necessary equipment.

This impression changed with the first pump cases. The nurses concluded that the cannulas were not what Odim was used to working with, after he made several negative comments about the equipment. In response, the nurses provided him with catalogues from which to order cannulas. However, he said he did not have the time to go through them. This had left the nurses at a loss as to how to deal with this issue.

Morale

Under the heading of morale, the nurses said they fully supported the withdrawal of anaesthetic services. They indicated it had been very demoralizing to lose so many children in a short period of time. They did not state in their document that the deaths of the children had brought about a loss of confidence in the program—however, that should have been apparent from the statement.

Role confusion

Under the heading 'Confusion Regarding Roles,' the nurses stated that it was stressful to have Odim asking the scrub nurse about the set-up of cannulas and pump lines, a matter not usually within their purview. To resolve this, the nurses arranged to have a perfusionist stand at the head of the table when the cannulas were being placed. It was noted that this problem could have been worked out in advance with a dry run (Exhibit 20, Document 278 P).

ANAESTHETIC CONCERNS

The two-page handwritten note that Ullyot prepared on behalf of the anaesthetists identified three points: input into the decision-making process, communication and follow-up.

Input into the decision-making process

The anaesthetists wanted to know if the cardiologist, Giddins, declined to refer any patient whom he initially saw to the surgeon, and on what basis such decisions were made. A related question was whether or not the surgeon, Odim, declined to perform surgery on any of the patients Giddins referred to him, and on what basis. The document asked if the anaesthetists could be included in the process of accepting or rejecting patients for surgery in Winnipeg. The anaesthetists recommended that case selection be made by a committee of representatives from cardiology, surgery and anaesthesia, before a decision was made to offer surgery in Winnipeg to the parents. Ullyot testified that during Duncan's tenure there had been extensive discussion between Dr. George Collins, Dr. Kim Duncan and herself before the first Norwood operation was attempted.

Communication

Under 'Communication', Ullyot's document noted that communication appeared to depend on individual initiative. For example, the anaesthetists had questions about why the intra-operative lines were changed in certain cases. The document contained the recommendation that there be weekly review meetings with an agenda and presentations. One of the issues that the anaesthetists wanted to see resolved in these meetings was whether X-rays would be taken in the operating room or in intensive care. It had been Duncan's practice to take X-rays in the OR, while Odim preferred to have them taken in the ICU. The anaesthetists preferred the OR, since it allowed for an immediate correction of problems in the OR if necessary. Odim preferred the ICU because it provided an opportunity to check for problems that might have arisen during the transfer from the OR to the ICU.

Follow-up

Under 'Follow-up,' the anaesthetists stated that the Morbidity and Mortality Rounds were "heavy on pathology, light on physiology and do not address morbidity." (Exhibit 203) They were concerned that only cases involving deaths were discussed, while there was ongoing concern about the extent of post-operative care needed for children who survived.

The anaesthetists recommended that each case be reviewed "to look for ways of smoothing the process. Deaths should be carefully examined to see if there were any difficulties with how the case was managed." In addition, they believed that it was important to look at more than the cases in which the patient died, since "not all good outcomes indicate a good approach." (Exhibit 203)

Ullyot testified that she hoped the committee would determine if the mortality and morbidity rates for the program were higher than they ought to have been. This could have been done, she felt, by matching children on a case-by-case basis with similar children who were cared for in other centres. In her testimony she noted that she believed it ought to have been possible to maintain a continuous record that would indicate, among other matters, the mortality rate. Nothing this rigorous was, in fact, undertaken.

It should be noted that this list did not address the anaesthetists' concern with surgical competence. The anaesthetists' reticence on this point continued.

ICU CONCERNS

Kesselman, on behalf of the medical staff of the PICU, prepared a document on June 3, 1994, which identified three areas of concern: surgical equipment, areas of responsibility and communication (Exhibit 227).

Surgical equipment/materials to be available in the PICU for emergency and elective procedures in the PICU

The PICU staff were concerned about the fact that they had not been prepared for the kind of surgical procedures Odim was undertaking in the intensive care unit. The PICU nursing staff had already asked Odim to give them some direction as to what essential equipment he thought should be kept in the unit in anticipation of the procedures he felt he had to perform there. This matter had been raised with him following the Ulimaumi case in March, but had not been resolved before the establishment of the committee. It should be noted that while some of the PICU nurses questioned whether or not it was appropriate to perform certain procedures in the PICU, Kesselman was only asking for more information on the materials Odim needed to perform these procedures. The other two points were linked.

Clarification of areas of responsibility in post-operative management and communication about patient status and proposed changes in therapy, both to the surgeon and from the surgeon.

These points refer to issues that have been discussed in the previous chapter. In particular, it would appear that Odim was still persisting in bypassing intensive care unit doctors and attempting to give medication orders to the PICU nurses. He was also requesting early-morning status reports via phone calls to his residence from nurses, whose schedules of providing nursing care to patients did not allow them enough time to make those telephone calls.

Kesselman testified that he presented these concerns at the committee meeting, and that Odim acknowledged that he would speak directly to the doctors on duty.

SURGERY AND CARDIOLOGY CONCERNS

Neither Odim nor Giddins provided written lists of issues to the committee. Odim said that he did express his concerns to committee members shortly after Wiseman's request. He testified that the issues he outlined were poor teamwork and communication, the need to consolidate the NICU and PICU and the need to reduce the number of anaesthetists. However, those attending that meeting did not recall Odim mentioning these concerns until much later in the summer and fall.

Giddins essentially said that he had no concerns that he felt he needed to bring to the committee. His view was that there was no reason to be concerned about what had occurred in the program to that point. He also was of the view that the anaesthetists' action was not appropriate. In response to questioning about what the Committee was asked to do and his view about the issues it was asked to address, Giddins said:

> Yes, but I can't—I still, I am still unsure of many of what you are calling concerns. The concerns that you are remarking on, I feel are issues that are inherent in a pediatric cardiac surgical program. Concerns over outcomes, concerns over ensuring the highest possible quality of program, those issues are standard issues as far as I am concerned.
>
> *Q.* Probably standard issues for any kind of surgery in any hospital anywhere; right?
>
> *A.* Yes.
>
> *Q.* You will agree, though, that having medical professionals withdraw services because of those concerns is a fairly unique experience?
>
> *A.* Yes, but I can't speak for the people or the practitioners that chose to do that.
>
> *Q.* I am not asking you to. I am just asking if for you this was something new?
>
> *A.* Yes. (Evidence, page 3,387)

Giddins was the acting medical director of the VCHC and in charge of the PCS program. Considering the state of affairs that existed in the program to that time, the circumstances surrounding the deaths of Jessica Ulimaumi and Vinay Goyal and the concerns expressed by the nurses and the anaesthetists, Giddins's view could easily be seen as an alarming statement. It also helps to understand why other parties were of the view that approaching Giddins with their concerns was an exercise in futility.

Ullyot testified that, as far as she could tell, the lists presented to Wiseman were never collated or directly presented to the committee as agenda items, although a number of the issues were raised tangentially. Wiseman's testimony on this point is unclear, although it supports Ullyot's assertion that the issues on the list were, for the most part, only discussed as and when they might arise in the individual cases that were being reviewed (Evidence, page 40,482).

THE ANAESTHETISTS AGREE TO RETURN

On May 24, 1994 the anaesthetists who were members of the section of pediatric anaesthesia issued a memorandum to Wiseman (with copies to Craig and Blanchard). This memorandum stated that a "workable method of conducting reviews and development" appeared to have been established. It concluded that "We agreed to resume cardiac anesthesia under the conditions discussed by the Committee on May 18, 1994." (Exhibit 19, Document 243) Those conditions included one that specifically required that only low-risk cases be done in Winnipeg until the review was complete, that anything other than low-risk cases be deferred or transferred and that emergency neonatal cases be sent to Saskatoon.

THE WISEMAN COMMITTEE BEGINS ITS DISCUSSIONS

No minutes or notes were kept of the committee's May 25 meeting. According to testimony, Wiseman asked each committee member to present his or her concerns. In putting forward the concerns of her colleagues, Youngson said:

> I remember being very apprehensive, very nervous. And I just talked about some of the cannulation issues and some of the air in the cannula type issues, and the fact that I was very uncomfortable having to—don't forget, I am saying this to Dr. Odim. (Evidence, pages 8,465–8,466)

Youngson said she also spoke about Odim's requirement for silence in the operating room during surgery, which was different from Duncan's approach. She said that Odim was pleasant and responsive to her concerns at the meeting. He indicated that he was sorry that she had these concerns, and that where possible he would attempt to rectify matters.

Youngson also testified that Odim asked McNeill if it would not be possible to shorten the induction period. According to Youngson, McNeill explained that this would be difficult, since the HSC was a teaching hospital and residents performed some of the functions undertaken during induction.

What was not discussed directly, according to Youngson was the mortality rate. When asked if anyone brought the mortality rate issue up for discussion, she testified:

> I don't think so, no. I didn't really discuss the high mortality rate. I just said that, you know, we were a little upset about what had happened. I don't think I came right out and said, you know, too many children are dying. I didn't put it like that. I said that what had happened up until that point was upsetting for us. (Evidence, page 8,472)

CORPORATE REORGANIZATION TAKES EFFECT

On June 1, 1994, the HSC's corporate reorganization took effect. From this date onwards, the Department of Pediatrics and Child Health and Pediatric and Child Health Patient Services (formerly Pediatric and Child Health Nursing) reported to the same vice-president, Helen Wright. The departments of Anaesthesia and Surgery reported to Susan VanDeVelde-Coke. The situation was further complicated by Bishop's departure on that date. According to documents provided to this Inquest, there were a number of acting heads, including Dr. John Bowman until September 15, when Dr. Brian Postl took over the position of head of Pediatrics and Child Health.

THE WORK OF THE COMMITTEE DURING THE MONTH OF JUNE

Throughout June and July, the committee reviewed cases. Issues such as morbidity and mortality, length of bypass and cannulation were discussed as they arose in individual cases, but not as separate, overarching topics. The meetings were held once a week in the late afternoon and generally lasted for two hours.

Odim said that during the early period of the committee meetings, there was discussion about ways in which the team could reduce the time spent in the operating room. At the same time he testified that attendance at team functions continued to be, in his opinion, poor.

McNeill felt that as time passed, the relations between team members deteriorated. She was pleased with the success that was being achieved with the low-risk operations, but felt there was growing pressure to move the program back to full service, a move with which she was not completely comfortable. As a result, relations between herself and Giddins and Odim, particularly at committee meetings, were marked by animosity. Giddins and Odim were eager to return to a full-service program, while McNeill resisted. Ullyot said that by a certain point in the committee's proceedings, there was conflict on this issue at nearly every meeting. Ullyot said that for the most part, Wiseman, Kesselman, Maas and Youngson did not participate in these discussions.

Kesselman said that he believed the committee was addressing problems that were situated in the OR.

> This is an issue with the surgeons and with the anaesthetists and the nurses there primarily, and that if they can agree that the program should be escalated at this point, for our part, we are able to comply with that and we can manage the patients. And my view really was more from that point of view, that I was willing to go along with that so long as they were able to agree on it. (Evidence, page 34,043)

Wiseman testified that at the outset the committee members clustered themselves into three camps: the surgeon and the cardiologist in one camp; the anaesthetists and the nurse in another; the perfusionist and the intensivist in a third. The last camp was seen to lie between the other two.

Wiseman said that at times he felt there was a need for freer communication on the committee than existed. He also noted that team building could not take place until honest communication took place; without that communication, the team would be built on false pretences. He did not, however, seem to have taken any steps to address this issue.

THE TRIP TO SASKATOON (JUNE 13–14)

At its first meeting on May 18, the committee had recommended that:

> The issue of an interim plan for the management of major emergency neonatal anomalies was raised. It was recommended that for the next 6 weeks the team transfer these infants to Saskatoon and participate in their management in the transferred setting. It was recommended that the cardiac surgeon, anaesthetist, and possibly one of the operating room nurses travel to Saskatoon and be involved in the infant's care. (Document 241)

While committee members were not involved in the management of all the cases that were referred out of province, in mid-June Odim, Swartz and Youngson travelled to Saskatoon to participate in the care of three patients. Odim even scrubbed in and assisted Dr. Roxanne MacKay, the pediatric cardiac surgeon in Saskatoon, with two of the operations.

Youngson said that she kept notes about any equipment used that was different from the equipment in Winnipeg. Odim had complained in the past about the pacing wires in Winnipeg, and she noted that a different wire was used in Saskatoon. While Odim said he did not want to use the wire that was used in Saskatoon, he did say that he would prefer to use the sort of needle driver that MacKay used. (A needle driver is a piece of equipment that the surgeon uses in suturing. The needle driver is used to grasp the tiny needles that are used in the suturing process.)

Youngson said that Dr. MacKay was very quick and proficient and that the team worked well together. In conclusion, though, Youngson testified:

> I don't think that there was anything really noteworthy that anybody saw, that was really any better or any different than what we have here in Winnipeg. (Evidence, pages 8,493–8,494)

Odim said that he hoped the exposure to different practices would encourage other team members to be less rigid in their approach to operating-room practice. He said the trip was not beneficial to him personally.

> I don't think that I learned much, because I shared the same sort of philosophy and concepts that the surgeon that I was visiting shared.
>
> *Question:* Dr. MacKay?
>
> *Odim:* That's right. She was in charge of her ship, she had an unified team and a small number of players. And I don't think our philosophies or beliefs in terms of how to develop a pediatric cardiac surgical team was radically different. So, personally, what it did, I did have some questions for her in terms of how she went about it, in that environment, and her concerns about the various components. (Evidence, pages 25,151–25,152)

Swartz indicated that in her view there was something to be learned from the Saskatoon experience, and that on her return she had waited for an opportunity to share it. She felt that the surgeon and the other team members had developed a close working relationship and they had a clear understanding of each other's roles. She thought that MacKay was a very fast surgeon and that one of the major differences between the Saskatoon and Winnipeg programs was the shorter period of time the Saskatoon patients were under CPB and in the operating room. She also noted small differences in the manner in which the anaesthetist performed his duties in the OR, but overall felt that the manner of anaesthetic delivery was not significantly different between the two programs.

She had wanted to share these thoughts with other committee members, but was frustrated by the fact that Wiseman did not place the matter on the agenda. Finally she asked for an opportunity to address the committee about the trip and was permitted to do so at a committee meeting in July. The committee devoted one meeting to listening to the members who went to Saskatoon and discussing their observations. Odim did not believe that the visit had any impact on the Manitoba program. He did say he believed that during this period, the people in the Winnipeg program were capable of doing high-risk cases.

THE CASE OF VM

VM was a five-year-old child who underwent a repair of an ASD on June 27, 1994. During the course of the operation the cannula inserted into VM's inferior vena cava became dislodged and fell out.

Odim testified that while he was explaining the child's anatomy to a student, the cannula rotated out of the inferior vena cava into the open right atrium. Hancock confirmed that in the process of showing the student the patient's anatomy, Odim manipulated the cannula to expose VM's defect. With the movement, the cannula tip flipped out of the IVC. However, Hancock testified, the cannula was still attached to the atrium wall. At that point there was a considerable amount of bleeding from the vein and if the cannula was not quickly reinserted and the bleeding controlled, there was potential for a serious negative outcome.

In this situation, normal surgical practice is to initiate what is termed 'sucker bypass', whereby bypass catheters that have suction capacity are used to take blood from the operative field back to the bypass machine. These catheters are usually used in surgery to remove blood from the surgical field, and normally the blood suctioned away from the field is not returned to the bypass machine. However, when sucker bypass is initiated, the suctioned blood is returned to the bypass machine to minimize blood loss.

There is a conflict in the evidence as to whether or not Odim notified the team of the cannula coming out and also as to who instructed the perfusionists to initiate sucker bypass.

McGilton testified that Odim did not inform the team that the cannula was out. Youngson testified that she was alerted to the problem by a perfusionist, who announced that the blood flows were down. In her testimony, Youngson said that Odim may have indicated that the cannula was out. Reimer, who was the anaesthetist for the operation, said that he did not recall Odim informing the team that the cannula had come out, although he soon became aware of the event.

Youngson testified that she expected Odim to tell the perfusionists to initiate sucker bypass. According to McGilton and Youngson's testimony, Odim did not give any instruction to initiate sucker bypass. Instead, according to McGilton, Youngson gave the instruction, which McGilton repeated to Todd Koga, the perfusionist. Hinam, the anaesthetic nurse, also testified that the instruction to go on sucker bypass came from Youngson, not Odim. McGilton put the suction cannula in place to take the blood away from the operative site.

Odim, however, testified that he instructed the team to go on sucker bypass. He did not recall Youngson suggesting they go on sucker bypass. Instead he recalled her yelling that they were on sucker bypass. He took this to be a message to the perfusionists that the suction cannulas were giving the return.

Throughout this process Odim was having difficulty reinserting the cannula. After attempting unsuccessfully to reinsert the initial cannula for a number of minutes, Odim successfully recannulated the child, using a different type of cannula. Once the cannula was replaced, the team continued with the repair.

While no known damage to VM arose from this event, the incident should have been recorded. In addition, an incident report should have been filed. However, there was no record of the event in Odim's operative report; nor did any member of the OR team complete an incident report. Additionally, the VM case was not reviewed by the Wiseman Committee.

Following this operation, McGilton started to make notes about operations in which she was involved. She speculated in her notes, as Youngson did in the notes she was keeping, that it appeared that Odim was not aware of the option of going on sucker bypass in such a situation.

THE JUNE 29 COMMITTEE MEETING

The evidence suggests that there were weekly meetings of the committee from May 25 to June 29. However, there are no notes or minutes from any of the meetings between those two dates. Additionally, the witnesses who were on the committee were unable to recall the discussion from those meetings with any degree of specificity. However, it is likely that during one of those meetings, the committee discussed the death of Gary Caribou. The first of the 12 deaths recorded in the any of the committee's notes and records, however, is that of Jessica Ulimaumi, whose case was discussed at the June 29 meeting.

On that day the committee met, with Dr. Heinz Reimer in the chair. Neither McNeill nor Wiseman could attend. McNeill had arranged to have Reimer sit as her replacement because he had been the anaesthetist for a portion of the Ulimaumi case, which was to be reviewed at the meeting.

One other case was discussed. This first case was that of KK, a four-and-a-half-year-old boy with an ASD. It was concluded that the operation had been straightforward and had not led to any concerns from nurses, anaesthetists or the ICU staff.

The second case was that of Jessica Ulimaumi. In reviewing the case, Odim told the committee that when he had first read her chart in the spring of 1994, before seeing her, he had been surprised to discover that she had not undergone surgery at an earlier date. He said that when he had examined her, however, he concluded that her clinical state was better than suggested by the information in the chart.

The course of the operation was reviewed. Reimer noted that there had been increasing difficulty in ventilating the patient during the lengthy bypass. According to Reimer's notes of the meeting:

> Some discussion took place as to whether the patch leak should have been repaired immediately as was done vs. waiting a few days for the myocardium to recover and then coming back to close the leak. Dr. Odim stated that his training was that if there was a mechanical problem it should be repaired immediately, and that this was done at the institution where he trained. Dr. Reimer pointed out that in that institution the total duration of cardiopulmonary bypass even with a re-repair was probably shorter than the duration of bypass for this child with the first repair alone. Dr. Reimer also stated that at the time the decision was made to repair the patch leak he could have been more vocal in pointing out the degree of inotropic support the baby was then on and generating more discussion as to whether the leak should have been repaired immediately or later. (Exhibit 67, HSC 81)

The child's stay in the PICU and the removal from ECMO were also reviewed. The minutes state that:

> During the cannulation one limb of the venous cannula was removed and not clamped. The child rapidly lost blood through this cannula and arrested.
>
> Dr. Odim acknowledged that he should have placed a clamp on the cannula. (Exhibit 67, HSC 81)

In her testimony, Youngson said that Mike Maas had not been present at the previous committee meeting. She had phoned Maas to alert him to the fact that the Ulimaumi case was going to be discussed at the next meeting. As a result, Dave Smith, the perfusionist who was present in the PICU when Ulimaumi died, attended the meeting. Youngson said there was a discussion of the events in the PICU. During that part of the discussion, Odim explained what he did, but made no mention of the fact that the cannula that had been removed from the child, had not been clamped and that blood had escaped through it. She testified that the following exchange took place.

> Dave, bless his heart, suddenly said, well, Dr. Odim, what exactly happened? I was behind my machine, I couldn't see what was going on at the bedside?
>
> And Dr. Odim sort of sat back for a second, and he said, well, actually, what happened was I forgot to clamp off the IV—I can't remember if it was the SVC or the IVC cannula, one of the cannulas that is attached to this Y. He pulled it out, and the patient bled to death out the other cannula before anybody noticed that this had happened.
>
> *Question:* Dr. Odim explained that's what happened at that time?
>
> *Youngson:* Yes. He said as well that there was a lot of activity around the bed, B. J. Hancock apparently was there. She wasn't, my understanding of what he said, she wasn't standing where she normally was standing in the operating room, and that she always clamps these lines before they are pulled out, and that she hadn't clamped this line, or he hadn't realized that she hadn't clamped this line, and he had pulled it out not realizing it wasn't clamped.
>
> Again, I sort of sat back, and I thought, aren't you nice, you are trying to blame B. J. for this. (Evidence, pages 8,475–8,476)

Youngson said that she believed Odim was familiar with the clamps under discussion, because he always referred to them in the operating room as slash clamps, while other HSC physicians referred to them as tubing clamps.

This was followed by a discussion about whether the decannulation should have been performed in the PICU or in the OR. Reimer was of the view that it would have been appropriate to have both operating-room nurses and an anaesthetist present for the decannulation. Odim told the committee that he had not requested operating-room nurses because they were reluctant to work weekends. Youngson said that this in fact was not the case. The operating-room nurses had never complained about working weekends. She insisted that if they had been called, they would have attended. She pointed out that on a number of occasions, operating-room nurses had been called in to perform surgery on weekends. They recognized that it was part of their responsibility.

Reimer also noted at the meeting that up to that time two children in the program:

> had suffered fatal outcomes largely due to the fact that they had VSD patch leaks which required re-exploration. Dr. Odim replied that the problem that had occurred in both patients was difficulty in exposure of the top portion of the VSD such that there was an actual fold in the VSD which had resulted in his interrupted sutures being placed wider apart than desired. He also said he had dis-

> cussed this with his assistants and was implementing a different type of retraction which would result in better exposure and hopefully circumvent the problem in the future. (Exhibit 67, HSC 81)

These minutes and the testimony about this case form the most extensive documentation about the committee's review of a case. It is apparent that this meeting was at times very tense and confrontational. However, it is not clear what, if anything, was resolved by this review. The meeting merely provided an opportunity for the key participants to give their interpretation as to what happened, instead of determining why problems had occurred and how things could be prevented in the future. It would appear that there was no discussion as to whether or not the team members, either individually or collectively, had sufficient experience to attempt this operation. It would appear that this would be the manner in which all of the reviews ended.

CONFLICT OVER OUT-OF-PROVINCE REFERRALS

Over the weeks following the first meeting of the Wiseman Committee, Giddins consulted with members of the Department of Anaesthesia to determine which cases were appropriate to take to surgery and which cases were to be classified as medium to high risk. Odim said that he did not participate in these discussions. The committee met weekly from mid-May through June. It is apparent that the question of whether a child was to be operated on in Winnipeg or sent out of province came to dominate many of the committee's discussions during this time. It is a sign of the rushed nature of the start-up of the committee that while it had a protocol stating that low-risk cases would be done in Winnipeg, there was no definition of low risk.

Odim testified that as the case reviews proceeded, there was an underlying and ongoing conflict over whether a child should be sent out of province or operated on in Winnipeg.

> There always seemed to be a battle between the anaesthesia group and the rest of the Committee on issues and the battle always centered around who to operate on, when to operate on them. (Evidence, page 25,135)

Odim's suggestion that it was anaesthesia against everyone else on the committee is contrary to the evidence. The conflict over doing higher-risk cases seems clearly to have been between anaesthesia representatives Ullyot and McNeill on the one side and Giddins and Odim on the other.

McNeill gave this description of an exchange between herself and Giddins over one referral:

> And he got angry with me and sort of jumped from his chair and leaned across the table straight at me, and raised his voice to me about what he was talking about, and took me aback at the time by, you know, the vehemence, if you will, of his statements. (Evidence, page 13,291)

Youngson testified that she witnessed the event. She said that Giddins "sort of came across the table" and "he just screamed at Ann." Youngson testified: "I just sort of sat back and I thought, well, that's it, I don't want that to happen to me." (Evidence, pages 8,555–8,556)

Odim also testified that it was never clear to him if the committee wanted to restrict operations to low-risk procedures or to low-risk patients. This was an important point that was never resolved.

In every operation, the risk of surgical complications is based on the operation itself, the condition of the patient and the interaction between the patient and the operation. A healthy patient generally presents a lower risk than one who is in poor health. While any patient having a minor operation would be at lower risk of having a complication, if the patient is in poor health, he may be considered a high-risk patient even if the operation is a low-risk procedure. Another patient, with no other medical problems, in good physical health and undergoing the same minor procedure, would be considered to be a low-risk patient. Therefore, two patients undergoing the same procedure may be viewed as presenting different risk levels.

It would appear that in assessing a patient for selection, Odim and Giddins considered only the risk associated with the procedure, while the anaesthetists also considered the risk associated with the patient's physical condition. Therefore, while from time to time, the surgeon and cardiologist wanted to perform a procedure that they saw as being one of low risk, the anaesthetists would object if they felt the risk was enhanced due to the condition of the patient.

Despite Ullyot's request at the start of the committee process, anaesthetists never became involved in the initial case-selection process. The only two members of the committee who attended the CVT conference continued to be Odim and Giddins. It was at this conference that Giddins presented cases to Odim for his consideration. The other members of the operating team were never invited to these conferences. Why Giddins and Odim never changed their procedures is a matter of speculation.

SWARTZ'S NOTES

One of the major criticisms of the committee process is that it involved a limited number of the people actually involved in the treatment of patients during the spring of 1994. Also, the committee focused on issues of teamwork, to the exclusion of competence and ability. Many of the people involved in the committee were reluctant to be completely frank about their concerns. However, it does appear that one member of the surgical team was prepared to raise these issues, but she was never asked to present her concerns to the committee.

Soon after the institution of the committee, Swartz prepared a four-page document outlining her general concerns with the program. She did this in anticipation of being consulted by the committee, however, the committee never undertook such a consultation, and therefore never heard her concerns.

The document (Exhibit 127) lists numerous concerns with the program that have been outlined in the previous chapter. However, it is worth reprinting Swartz's second point.

> Are some cases of a degree of difficulty beyond the training, expertise, clinical experience and judgement (as a result of experience) of our surgeon. It is one thing to read about a procedure, another to see it, another to do it and another to do it well and recognize the difficulties and complications and know how to avoid or solve these problems.
>
> I am referring to our high morbidity and mortality as evidence in themselves in general. (Exhibit 127)

These are strong words. One wishes one could say that it was simply unfortunate that they were never spoken at a committee meeting. But, in fact, it is far more than unfortunate. Swartz's comments represent the very issue that had brought about the anaesthetists' actions to begin with and permeated much of the thinking of some members of the committee throughout 1994. Silence on the point of whether or not competence was an issue allowed the matter to remain unaddressed.

CRAIG AND ODIM MEET

One morning in June, Craig asked to meet with Odim. Blanchard had told Craig that Odim had not felt supported by the anaesthetic group and Craig wanted to find out what Odim was concerned about with respect to the anaesthetists and to see if he could address Odim's concerns. Craig recalled that Odim expressed the view that the number of anaesthetists involved in the Pediatric Cardiac Surgery Program was too high. He felt that there should be fewer anaesthetists doing pediatric cardiac surgery in order to maximize their skills and knowledge. He felt—as did his predecessor Duncan—that with the low number of open-heart cases actually being performed in Winnipeg, having four anaesthetists rotating into the operations diluted their experience and made it difficult for them to develop appropriate levels of skill. Craig says that he listened to Odim voice his view but did not undertake to make any changes.

Craig held a different view as to the number of anaesthetists needed for the program.

> I recognize it as a concern, but I don't really see the relevance. If you look at the anaesthetists, including myself, who practice in the teaching hospitals, St. Boniface, HSC, adult, pediatric, I would guess well over half of them aren't full time doing clinical anaesthesia. I think that's good, that some of them are doing research, some of them are working in the ICU. So to me it is the reality of modern anaesthetic practice, same here as elsewhere.
>
> So to say that you have to have an anaesthetist working five days a week in the operating room or they are not a good anaesthetist, or they are not as good as if they were, it doesn't make sense. So I would like to put it in a different context; if somebody wanted to expose to me the logic as to why part time is bad, I would be delighted to look at it, but I don't believe it is. (Evidence, page 34,559)

Craig also testified that he did not believe that the fact that each of the anaesthetists was part-time reflected a lack of commitment on their part, an issue of concern to Odim.

THE CASE OF ARIC BAUMANN

ISSUES

Aric Baumann underwent heart surgery on June 30, 1994, and died on August 21 after spending 52 days in the PICU. His death was due to pulmonary vein stenosis, an undiagnosed congenital defect. It is essentially unresponsive to treatment and usually fatal.

This case gave rise to the following questions:

- Could Aric's pulmonary vein stenosis have been identified before surgery?
- If it could have been detected earlier, could Aric have benefited from a heart-lung transplant?
- Was Aric a high-risk patient at a time when the program was not undertaking high-risk cases?
- Were his parents provided with sufficient information to allow them to give informed consent to the procedure?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Aric Baumann was born on December 7, 1993, at St. Boniface General Hospital. He was born prematurely at 36 weeks gestation and weighed five pounds two ounces. He was the second child born to Curtis and Deanna Baumann. Shortly after his birth, Aric was noted to be cyanotic and to have a heart murmur.

Giddins examined Aric at the St. Boniface Hospital soon after his birth. Deanna Baumann testified that Giddins told her and her husband that Aric had a hole in his heart, but that he would likely not need surgery for a number of years.

Giddins subsequently saw the family at the Heart Centre on January 3, 1994. Giddins observed that Aric's chest was clear, although his breathing was shallow with mild in-drawing. Aric's oxygen saturation level was 96 per cent; however, this value dropped when he exerted himself. The results of an electrocardiogram suggested that Aric had:

- enlargement of his right atrium
- hypertrophy of his right ventricle.

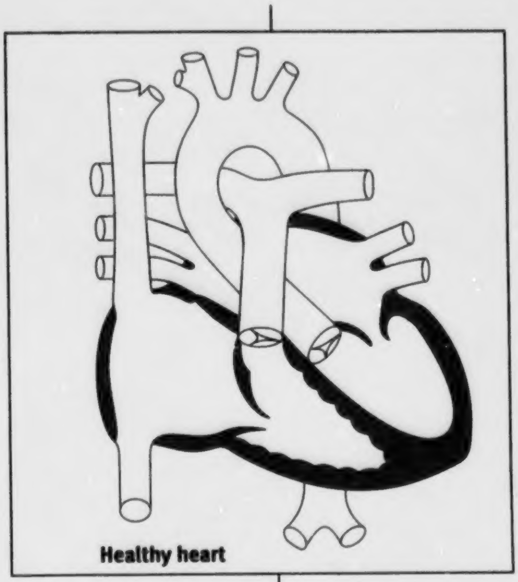
These results, together with the clinical findings, suggested that Aric had a partial atrioventricular canal defect with overload of the right side of his heart. A partial atrioventricular canal defect is similar to a complete atrioventricular canal defect, except that the child still has separate valves between the left collecting chamber and the left ventricle and between the right collecting chamber and the right ventricle.

An echocardiogram confirmed the diagnosis of a large degree of atrial shunting, with moderate to severe right atrioventricular valve regurgitation and a moderate elevation of pulmonary pressures. In other words, Aric had what is termed a primum atrial septal defect. This is a hole between the top chambers of the heart. The hole was thought to be large, due to the amount of blood that was shunting. This condition is usually associated with minor valve problems and leakage.

Giddins said it was his approach to attempt to surgically correct the defects that Aric was suffering from when the child was between two and three years of age. Therefore he did not recommend sending Aric to surgery at that time.

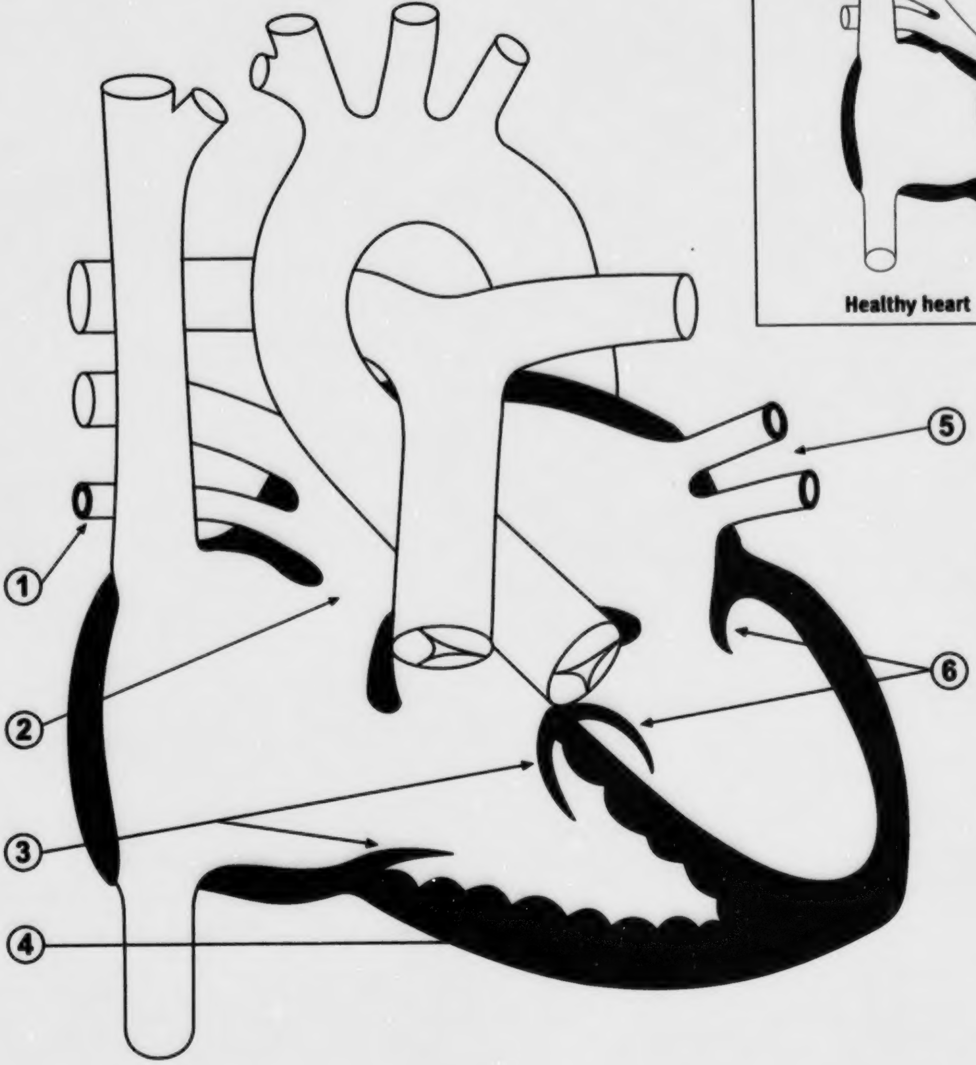
In a January 3, 1994, letter to Dr. Cheryl Simmonds, Aric's doctor, Giddins confirmed that Aric had tachypnea (rapid breathing) with mild in-drawing, which were symptoms of mild right-heart volume overload and pulmonary edema. Since Aric was thriving, his liver was normal, and his peripheral pulses and perfusion were good, Giddins advised that there be no specific intervention at that time and that a follow-up visit take place in three months. However, he cautioned that with such a large atrial septal defect and valve regurgitation, a heart catheterization followed by a definitive repair would be necessary if Aric's condition deteriorated.

At Aric's follow-up appointment on April 13, Giddins found Aric's condition to have remained relatively stable, although there had been some deterioration. Aric's oxygen saturation level was 86 per cent. Both ventricles were hypertrophied, and an echocardiogram revealed moderate to severe left atrioventricular valve regurgitation. Considering the changes and the continued atrial shunting, Giddins arranged for Aric to undergo a heart catheterization in May. It was becoming apparent that a surgical repair might be required in the near future.



Healthy heart

Diagram 7.1 Aric Baumann – pre-operative heart



1 – Right stenotic pulmonary vein (not detected prior to surgery)
2 – Partial atrioventricular canal defect (septum primum defect)
3 – Deficient tricuspid (right atrioventricular) valve (not detected prior to surgery)
4 – Right ventricular hypertrophy
5 – Left stenotic pulmonary veins (not detected prior to surgery)
6 – Deficient mitral (left atrioventricular) valve (not detected prior to surgery)

Before the catheterization took place, however, Aric became very ill. When his parents took him to hospital on April 30, he was diagnosed with heart failure and treated with diuretics. He also required treatment with antibiotics for ten days for an ear infection. During his stay in hospital, an echocardiogram was done on May 2. This showed:

- a partial atrioventricular canal defect
- a torrential left to right shunt through a large primum atrial septal defect
- severe right atrioventricular valve regurgitation
- moderate pulmonary hypertension.

The shunt was diagnosed as torrential because four hundred per cent more blood was flowing into Aric's lungs than was normal. A cardiac catheterization performed on May 5 confirmed those findings and indicated that there was also mitral stenosis. Aric's heart failure was brought under control and he was discharged home on May 8.

One of the issues in Aric's case was the fact that the defect Giddins identified did not normally create the degree of hypertension that Aric was suffering from, so early in life. Odim attributed the hypertension to the mitral stenosis, and to the hole in part of the atrial septum above Aric's valves.

THE DECISION TO OPERATE

On May 9, 1994, Giddins and Odim identified Aric as a candidate for surgery in the near future, much earlier than had been previously anticipated. A date for surgery was set for mid-June, although the operation was subsequently postponed because Aric was suffering from a mild cold.

CONSENT

On Thursday June 16, Odim met with the Baumann family. He testified that he explained the risks to the family in detail. Deanna Baumann testified that they were told that the operation involved placing a patch over the ASD, a procedure that would take only 15 minutes, although it would take several hours to prepare their son for this repair. She recalled that Odim gave them no indication of any risk, and they were led to believe that Aric would be home within seven to ten days following the operation. Odim testified that he could not recall discussing the slowdown in the program with the Baumanns. He did say that during this period he did inform parents that the program was undergoing a slowdown and reorganization.

> During that summer when we were seeing patients in clinic, it was quite often patients wanted to know when they would have their surgery. And the families who were being seen in the clinic, sort of, many of them are anxious to get a surgical date. And during those conferences in the office, I did mention to families that the program had slowed down. I did mention to families that that's why we don't have a particular date, or could not promise them when we might be able to do an operation. I did mention to families that the team was having difficulties and problems, and we are trying to sort that out. (Evidence, page 25,199)

However, Deanna Baumann testified that she and her husband were never told anything about any problems in the Pediatric Cardiac Surgery Program.

While this case had first been presented to the CVT conference before the May 17 program slowdown, the operation did not take place until after the Wiseman Committee had started its deliberations. Giddins was asked if this case was taken to the committee since it involved open-heart surgery. He testified: "No, because atrial septal defects were in the general category of being low risk." (Evidence, page 3,862) He testified that he had reached this conclusion because there had already been two ASD cases undertaken after the May 17 slowdown. In his testimony, Giddins said he believed that this was a very low-risk operation, with the fatality rate being between zero and five per cent. This sentiment was also expressed by Odim, who said he believed the operation to be low risk.

However, in a letter that he wrote to Simmonds on August 22, after the child's death, Odim stated:

> In light of the torrential left to right shunt, pulmonary hypertension, elevated pulmonary vascular resistance despite oxygen therapy, and relative left-sided hypoplasia, we all knew that Aric would be at a substantially higher surgical risk [underlining added] than the usual ostium primum defect lesion. (Exhibit 2, page BAU 34)

In his testimony, Odim said he still believed Aric to have been a low-risk patient, although the risk was greater than the five per cent risk he would assign to an ASD. He declined, however, to assign a percentage value to the risk. Odim also indicated that he gave the parents the following information about the risk to Aric:

> We were very concerned about the issue of the pulmonary hypertension, the issue of the increased pulmonary vascular resistance, and cautioned mom and dad that the post-operative course could be very difficult if the child were to have what we call pulmonary hypertensive crisis, remain intubated for a long time, need additional types of drugs to help with the pulmonary bed. (Evidence, page 25,179)

Swartz had a different view of the risk involved in the case, although she agreed to proceed with the case when it was discussed at the pre-operative conference. She testified:

> I thought this was a high risk case, just the very fact that he had pulmonary hypertension. I wondered why we were going ahead with it. I might even, you know, I can't remember, I can't remember exactly if I talked to Dr. McNeill. (Evidence, page 15,892)

From the testimony presented to this Inquest, it would appear that Aric Baumann's lesion might justify calling this a low-risk case, as indicated by Odim and Giddins. However, the seriousness of his pulmonary hypertension and increased pulmonary vascular resistance suggest that the risks associated with this case were much higher. While he might not be a high-risk patient, at the very least he was on the high end of the low-risk rating.

There is a significant difference in the testimony of Deanna Baumann and Odim as to the amount of information that was provided to the Baumanns about both the particular level of risk in the case and the state of the overall program. On this point, Deanna Baumann's evidence is to be preferred.

ADMISSION TO THE HOSPITAL

Aric was admitted to the Children's Hospital on Wednesday morning, June 29, for elective surgery the next day. The examinations conducted on admission found his chest clear with mild in-drawing. That evening, Deanna Baumann gave her written consent for surgery.

THE OPERATION—JUNE 30

On the morning of June 30, Aric underwent a repair of a partial atrioventricular canal defect. This was accomplished by placing a patch closure over the septal defect. There was no ventricular component to this A-V canal malformation. In his operative report, Odim noted that the atrioventricular valves were malformed.

The operating team is set out in the accompanying table.

TABLE 7.1: Persons involved in the operation on Aric Baumann, June 30, 1994

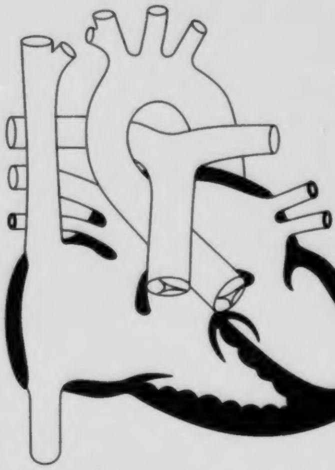
OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	B. J. Hancock
Anaesthetists	J. Swartz, S. Goheen (resident)
Scrub nurses	C. Youngson, H. Skomorowski
Circulating nurses	C. Weber, B. Zulak
Perfusionists	C. McCudden, T. Koga

The anaesthetic preparation and induction time was one hour and twenty-eight minutes. There was no indication of problems during this period. The total surgical time, from beginning the incision to closure of the incision, was five hours. There were two periods of cardiopulmonary bypass that totalled two hours and twenty-nine minutes. The aortic cross-clamp time was forty-four minutes.

TABLE 7.2: Length of phases of the operation on Aric Baumann, June 30, 1994

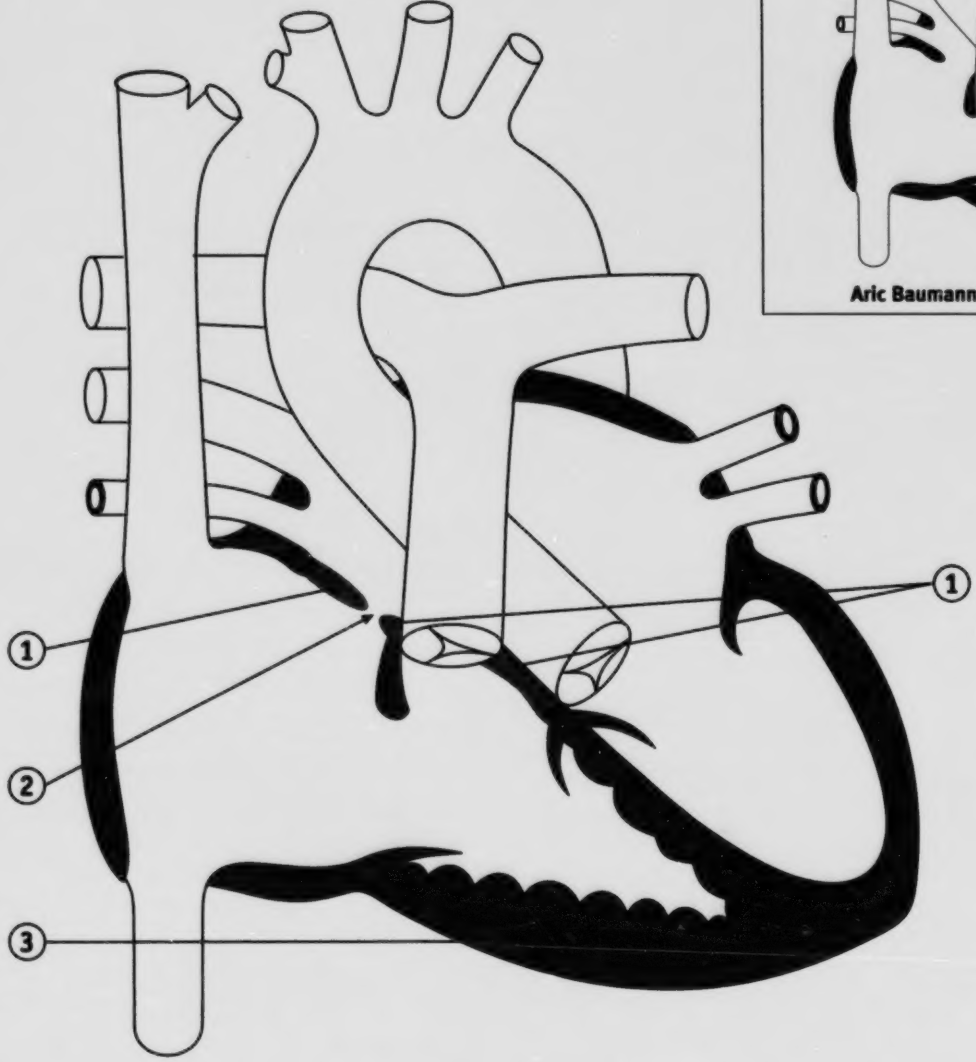
Phase of the operation	*Time taken*
Induction	1 hour 28 minutes
Bypass	2 hours 29 minutes
Aortic cross-clamp	44 minutes
Total surgical time	5 hours
Total operating-room time	6 hours 53 minutes

In his operative report, Odim said that there were problems during rewarming in getting Aric's heart to beat in the proper rhythm. Aric experienced third-degree heart block, a lack of synchronization in the contractions of the upper and the lower chambers of the heart. Third-degree heart block is the most serious form of heart block.



Aric Baumann – pre-operative heart

Diagram 7.2 Aric Baumann – post-operative heart



1 – Patch closure of partial atrioventricular canal defect
2 – Fenestration of patch closure of partial atrioventricular canal defect
3 – Cardiomegaly with right ventricular hyptertrophy

Because of Aric's problems with heart block, Odim inserted a pacemaker. However the pacemaker failed to capture. Aric was put back on bypass, and all aspects of the pacemaker were rechecked. The pacemaker wires and battery were changed. When Aric was taken off bypass a second time, the pacemaker again failed to capture. However, he eventually developed a normal heart rhythm without the assistance of a pacemaker and was taken to the PICU.

In his report, Cornel wrote, "The decisions made at the time of operation were reasonable surgical judgments." (Exhibit 353, page 48) He stated that Odim was correct not to attempt to address problems with the mitral valve and the tricuspid valve. It was reasonable, Cornel said, to expect that the surgical measures he had taken would provide Aric with sufficient relief.

POST-OPERATIVE COURSE

A child undergoing surgery for an ASD would normally be expected to spend no more than ten days in hospital. This did not happen in Aric's case. Instead, he spent 52 days in the PICU, ultimately dying there. While his condition in the PICU was initially stable, by July 4 his condition was starting to deteriorate.

On Monday, July 4, (Aric's fourth day in the PICU) a PICU resident noted that Aric had had three episodes of pulmonary hypertension in the previous 48 hours. The right upper lobe of his lung had collapsed and he was slightly fluid overloaded. By Tuesday, the right upper lobe of his lung had re-expanded and his oxygen saturation level was 100 per cent. He showed varying degrees of heart block and needed the pacemaker to control his heart rhythm. During this period there were also problems in getting the pacemaker (or possibly the leads) to operate properly. On Wednesday, Aric continued to have problems with heart block. He also had low blood pressure, reduced blood flow to his tissues, a decrease in his oxygen saturation level and a drop in his urine output. In addition, he was suffering from a chemical imbalance. (He was in metabolic acidosis.)

From Thursday, July 7 to Wednesday, August 17, Aric's condition slowly deteriorated. He remained ventilated for his entire stay in the PICU. The major problems he had during this period were:

- Arrhythmias (abnormal heart rhythms): these required frequent manipulation of his pacemaker.
- Pulmonary hypertensive crises (high blood pressures in his pulmonary arteries): these required drug treatment (phenoxybenzamine), which did result in his condition becoming slightly more stable.
- Congestive heart failure, with pulmonary and peripheral edema (decreased heart function with fluid retention in the lungs and in the arms and legs), with worsening of the atrioventricular valve regurgitation: this was treated with large doses of diuretics.
- Episodes of sepsis (serious infections of the blood): these were treated with antibiotics.
- Pneumonia and respiratory distress syndrome (lung infections and decreased lung function): these meant that Aric needed to be ventilated by machine.

Giddins testified that it was expected that, since the repair had been successful, the high pressures in Aric's pulmonary arteries should have been reduced. However, this did not happen. Aric had ongoing problems with the vessels that carry blood to the lungs.

This was a very trying period for the Baumann family. For the entire time he was in the PICU, Aric had a tube down his trachea and was connected to a ventilator to assist his breathing. At one point in mid-July, the family was told that it looked as if Aric would only last another 48 hours. The distraught family arranged for baptism at that time. However, Aric rallied and survived for another month.

At the same time, the medical staff continued to search for the cause of Aric's deterioration. One of the people involved was Dr. Cameron Ward, a cardiologist who had started working with the Heart Centre in July. Ward suggested that there was a constriction of the pulmonary veins. This is also known as pulmonary vein stenosis. Over time, the pulmonary veins of patients suffering from this congenital disease become progressively narrow. It is not known what causes this process to start, nor do doctors know how to stop the process. Witnesses testified that while the condition is often fatal, there are instances of the condition arresting on its own. In some cases a patient might be left with one functioning lung and one non-functioning lung. The only definitive treatment was a full lung and heart transplant. However, this was rarely feasible with patients of Aric's age and size.

A cardiac catheterization was conducted on August 18. When compared with a catheterization conducted in May, the results indicated that Aric did indeed have pulmonary vein stenosis. Giddins testified that when he had examined the catheterization results in May he had not looked for signs of pulmonary vein stenosis; nor had he seen any. Following the diagnosis of pulmonary vein stenosis, he re-examined the May results and testified that he could see some signs of vein narrowing. However, this narrowing was much more extreme in the August catheterization.

Giddins testified that if he had diagnosed pulmonary vein stenosis in May, he would have still recommended proceeding with Aric's surgery. He said that the stenosis did not increase the surgical risk to the child. Furthermore, he said that he would not have recommended any change in Aric's post-operative care if he had known of the stenosis.

Odim testified that during the course of the operation, he could not see any sign of pulmonary vein stenosis. He also testified that, had he known of the stenosis, he would have still recommended proceeding with the operation.

Aric's pulmonary vein stenosis was extreme by the time the condition was diagnosed in August. Giddins, in consultation with Ward and Odim, concluded that the problem was not treatable. In a letter written to Simmonds after Aric's death, Odim wrote, "This was a rather unfortunate anatomic arrangement which was not entirely appreciated at the outset. The prognosis for this type of problem is very poor with the only option to date being a combined heart lung transplantation which in this age group continues to be an experimental venture." (Exhibit 2, page BAU 35)

Giddins, Dr. Fiona Fleming and Hawkins met with the family on August 20. It was explained to the Baumanns that a transplant was not possible in this situation and that there was no other treatment for Aric's condition apart from comfort care. The parents agreed to a recommendation to stop treatment once all of the family had been called together. Aric died in his grandmother's arms at 1134 hours on August 21, 1994.

AUTOPSY

On August 22, 1994 Dr. Joseph de Nanassy performed an autopsy. A preliminary report was issued on September 7, 1994, but the final autopsy report was not completed until February 14, 1995. As a result, the Baumanns did not receive the autopsy report until mid-February. The delay in the completion of the autopsy report in this and a number of subsequent cases will be discussed in Chapter Nine. At the family's request, the autopsy was restricted to an internal examination of the chest and abdomen.

De Nanassy confirmed that, while the surgical repair was intact, Aric suffered from pulmonary vein stenosis. This was greater on the left side. The pathologist concluded that the pulmonary vein stenosis would not have been amenable to corrective measures. In his report, Taylor indicated that there was a tiny hole or fenestration in the patch. However, he testified that he could not identify when or how the fenestration was made, noting that in some cases, surgeons will make such a fenestration to ease pressures. The fenestration did not contribute to Aric's death.

FINDINGS

The evidence presented to this Inquest gave rise to the following questions:

- Could Aric's pulmonary vein stenosis have been identified before surgery?
- If it could have been detected earlier, could Aric have benefited from a heart-lung transplant?
- Was Aric a high-risk patient at a time when the program was not undertaking high-risk cases?
- Were his parents provided with sufficient information to allow them to give informed consent to the procedure?
- What was the cause of death and was it preventable?

These are also the questions that the Baumann family wished to see addressed.

Could Aric's pulmonary vein stenosis have been identified before surgery?

Cornel questioned why the pulmonary vein stenosis was not identified pre-operatively. In his evidence, he stated that he was aware that pulmonary vein stenosis can be difficult to detect and may not manifest itself as a serious condition until the child is older. However, generally, with close observation, the onset of the disease can be identified relatively soon. Cornel also felt that the condition could have been identified sooner than it eventually was. If it had been, the difficulties experienced by the family in watching their son deteriorate might have been alleviated.

He agreed with Giddins and Odim that the fact that Aric had pulmonary vein stenosis would not necessarily have meant that the operation should not have proceeded. Cornel stated that, although it can be a fatal condition and is not treatable, sometimes pulmonary vein stenosis can stop progressing on its own for no known reason. He felt that the decision to operate on Aric, even in the face of that information, would not necessarily have been an incorrect one.

Giddins indicated that in retrospect he could detect signs of the stenosis on the May 1994 catheterization. In contrast, Dr. Walter Duncan stated that after reviewing the pre-operative reports, he could not find any evidence that would have led him to conclude at that time that Aric had pulmonary vein stenosis.

- **Finding**

It would have been desirable, particularly from the parents' perspective, to have been aware of the stenosis. However, it appears from the evidence that it was not unreasonable for Giddins to have failed to detect the stenosis in May. Furthermore, it also appears that medical staff would have recommended the course of treatment that was carried out, even if the stenosis had been identified.

Would Aric have benefited from a heart-lung transplant?

On this point Duncan and Cornel stated that "This would have been a difficult judgment call with regard to operability. Only other option would have been no treatment or heart and lung transplantation – {virtually not available in Canada in this age range....}." (Exhibit 354, page 10) In his testimony, Giddins said that such transplants are still very experimental.

- **Finding**

It does not appear that a transplant would have been a realistic option in this case.

Was Aric a high-risk patient at a time when the program was not undertaking high-risk cases?

- **Finding**

Questions of risk are not easy to quantify. Aric underwent a relatively low-risk procedure. However, he was a higher than usual risk patient. Both Odim and Giddins maintain this was, relatively speaking, a low-risk case. Given the circumstances of the program and the circumstances of the patient, Giddins should have consulted with McNeill about whether or not to transfer Aric to another heart centre. However, no consulting witness has identified any surgical issues that led to Aric's death or suggested that this was a high-risk case. While the risk may have been higher than for a simple ASD, it is fair to conclude that this was not a high-risk case.

Were Aric's parents provided with sufficient information to allow them to give informed consent to the procedure?

- **Finding**

While it may have been appropriate to undertake this operation in Winnipeg, the Baumanns ought to have been clearly informed of all risk factors involved in this case before being asked to consent to surgery. For there to be informed consent they would have had to have been told of the specific risk in Aric's case and of the slowdown in the program. The evidence tends to suggest that Aric's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

What was the cause of death and was it preventable?

- **Finding**

In this case, there is no dispute over the cause of Aric's death. He died as a result of pulmonary vein stenosis. In his report, Duncan stated simply that this was an unavoidable death and not a surgical or management issue. Dr. Christian Soder felt that the cardiac condition from which the child was most at risk (the pulmonary vein stenosis, which was only identified in retrospect) was inoperable.

Aric's death was not preventable.

KIM DUNCAN'S VISIT

In July 1994 Dr. Kim Duncan visited Winnipeg and met with Youngson, Giddins and several of the perfusionists. He recalled that they spoke to him of the tensions within the program. Following those discussions, he met with Dr. Helmut Unruh, the acting section head of cardiovascular and thoracic surgery. Duncan testified that:

> My comments to Helmut Unruh were, was there any way, or was it possible for him to observe, or possible for somebody else to observe or participate in order to see if there were, in fact, problems. I didn't—
>
> *Q.* You asked Helmut if it was possible—
>
> *A.* My comment to him was, if you have four people, who I think are quite credible people, saying there are some difficulties in the operating room, then there is probably at least reason for somebody to look into it. (Evidence, page 30,595)

Unruh testified that he could not recall the details of this conversation. Duncan also spoke with Odim. The two men agreed that the program should be serviced by a small number of anaesthetists. However, Odim left Duncan with the impression that he felt the program was running well.

THE CASE OF SK

SK was born on April 13, 1984. At three years of age, she was diagnosed with an atrial septal defect. Odim saw her on June 7, 1994. At that time he determined surgery was in order. An echocardiogram showed an atrial septal defect, with left to right shunting and significant volume overload.

On July 7, 1994, SK underwent surgery to close her ASD. In the notes that Youngson prepared after the operation, she wrote that there had been problems with the cannulation. In particular, Youngson wrote, it was necessary for Odim to replace a number of sutures that had been cut or torn during cannulation. Youngson concluded, "This is something that happens on a regular basis – purse string sutures are cut or torn when Dr. Odim is cannulating, often damaging the vessels." (Exhibit 20, Document 278 D)

In his testimony Odim said that he could not remember difficulties with cannulation or tearing the vessel in this case. There is no mention of any such incident on the medical chart.

THE CASE OF KZ

KZ was born on March 29, 1987. At one year of age, she was diagnosed with an atrial septal defect. Surgery was delayed until her seventh year.

On July 11, 1994, KZ underwent a suture closure of her atrial septal defect. Her oxygen saturation level was low during the first attempt to take her off bypass. Initially Odim thought that the problem may have arisen as a result of the anaesthetist having difficulties ventilating the patient. Dr. Harley Wong, who was the anaesthetist for this operation, indicated that KZ was receiving 100 per cent oxygen and that her lungs were being well-ventilated. Odim then determined that KZ had a left to right shunt. As a result, he determined that it was necessary to go back on bypass and reopen her heart. Odim discovered that he had mistakenly sutured KZ's eustachian valve to her left atrium. According to Odim, the eustachian valve is

> ... a valve that is used normally in utero to channel blood to the left side of the heart, because as you all know, the lungs aren't being used so there is not a great demand to have blood going to the right side of the heart into the lungs to pick up oxygen. So it takes the placenta return from mom, in the child, and channels some of that oxygenated blood directly over to the left side.
>
> When children are born, many a times this structure involutes, it is not readily apparent, and in some children it is actually quite prominent and you can see it, in many you don't see it and it is not there. Again, it is a white veil like tissue structure.
>
> And in the setting of a hole that's really at the mouth of that lower IVC, you can mistake that lower rim for your ASD when, in fact, it could be part of this valve. (Evidence, pages 25,212–25,213)

By trapping the eustachian tube in his stitch, Odim obstructed the inferior vena cava and oxygen starved blood was misdirected into the left atrium. Odim corrected his error and the atrial septal defect was again closed. KZ recovered and was discharged home on July 15, 1994.

Wong viewed the suturing of the eustachian valve as a serious matter. He mentioned it to McNeill, who brought it up for discussion at the Wiseman Committee. While Wong did not attend the committee meeting, he said McNeill reported back to him that Giddins and Odim had explained that this was a recognized complication in this sort of surgery. Wong had never heard of the complication. He examined Dr. Carol Lake's textbook, *Pediatric Cardiac Anaesthesia*, and could find no mention of suturing over the eustachian valve as being a known complication.

In her testimony McGilton said that she had never heard of this problem in cardiac surgery before. In fact, she testified that up until that point, she had never heard of a eustachian valve.

Giddins, Hancock, and Odim asserted that suturing a eustachian valve was a recognized complication of repair of ASDs when there was a prominent eustachian valve. However, neither Giddins nor Hancock had ever known of a case where this had happened. Odim said he had seen it happen in every institution he had worked in, but could give no indication of how often it happened. This Inquest was also given excerpts from one textbook and two journal articles that discussed this issue.

It would appear from that material that oversewing the eustachian valve is a rare but recognized complication in the repair of ASDs. In the case of KZ, oversewing the valve did lengthen the operation, although the patient's health was not compromised. However, the event did little to allay the nurses' and anaesthetists' concerns about Odim's surgical abilities.

THE JULY 13 WISEMAN COMMITTEE MEETING

On July 13, 1994, Giddins chaired a meeting of the committee, which was attended by Maas, Odim, McNeill and Youngson. The case of JM (outlined in the previous chapter) was discussed that day. It involved a successful Fontan operation that was carried out on a three-and-a-half year old boy. The key issue in the operation was the anaesthetist's decision to insert a line into the right internal jugular vein. Anaesthetists regarded such lines as being of considerable importance in monitoring their patients. However, in this patient, Odim had had the line relocated because he was worried that such lines could lead to a narrowing of the vein. This was a particular problem in patients undergoing Fontan-type procedures, since the veins might be needed undamaged for future surgery. As a result, the anaesthetists agreed not to place internal jugular lines into patients undergoing Fontan-type procedures. (Exhibit 20, Document 278 E)

THE JULY 27 COMMITTEE MEETING

The committee met on July 27. Unfortunately there are no minutes available of that meeting. In many ways, this appears to be have been a pivotal meeting in the committee's history. It was at this meeting that Giddins proposed that the program was ready to resume full capacity. The committee had been in place for a little over two months. However, it had not produced any statistical review; nor was there any consensus as to whether or not the team should return to full operation.

McGilton, who attended the meeting in Youngson's place, opposed going to higher-risk cases because of concerns arising from the VM and KZ cases. She testified:

> So I said that, no, as a group we do not feel comfortable in moving on—
>
> *Question:* Okay.
>
> *McGilton:*—to higher risk cases. And Dr. Giddins and Dr. Odim said why. So I said that even though things had been going well, that the children were doing well, things hadn't been smooth in the OR and we had concerns with that. So, again, they wanted to know what. So, I gave the example of [VM], the cannula coming out and Dr. Odim—
>
> *Question:* Having to go on sucker bypass?
>
> *McGilton:* And having to go on sucker bypass. And as I was talking about this, Dr. Odim said, oh, you mean when I was giving the student the explanation about the anatomy. Which to me didn't really make sense anyway, because I didn't understand what the connection was. But that was his response. And I brought that up and I brought the eustachian valve up, and Dr. Giddins got very, very angry, very upset. (Evidence, pages 10,588–10,589)

McGilton testified that she had explained how the eustachian valve had been sutured over, requiring the patient go back on bypass. According to her testimony:

> And Dr. Giddins then raised his voice, got very angry and said that he could show me an anatomy book and show me how easy it would be to make that mistake, and it's a common thing to do. And

> basically, in so many words, you are just a nurse, what do you know? And Dr. Odim made the same kind of comment, you are not a surgeon, you are a nurse, or whatever.
>
> I just stuck to my guns and said, well, that may well be and, yes, the children did do well, they made it through, that was true, but we just didn't feel that things had gone smoothly and we don't feel comfortable moving on. (Evidence, pages 10,589–10,590)

McGilton said she felt that Odim did not exhibit the anger that Giddins demonstrated. Instead, his comment was more along the lines of a joking statement that a nurse's comments were not worth considering.

McNeill corroborated McGilton's testimony.

> But the overall reaction was not very receptive on the part of cardiology and the cardiac surgeon. They questioned her position in terms of, well, her expertise in making the criticisms that she had. And I guess it was sort of like negating her concerns on that basis. (Evidence, page 13,288)

In his testimony, Giddins said he could not recall anyone being told that their opinion lacked validity because that person was not a surgeon. Odim testified that he recalled the exchange, but said that he did not make any comments at the time. McGilton testified that at the end of the meeting, Wiseman told her she was not making things easier. Wiseman said he could not recall making the comment.

It should be noted that the suturing-over of the eustachian valve was a far from minor matter. As noted above, the anaesthetist involved in the operation had also been disturbed by the problem. It was an appropriate topic for discussion and for anyone to raise as a matter of concern.

Wiseman testified that out of deference to McGilton's objections, the decision was made not to return to full service. However, it was clear that pressure was building for a return to such service. In two weeks time, Wiseman himself recommended that the team start doing cases that were of medium risk.

McNeill said that, from her perspective, the pressure to return the program to full capacity came from a number of sources. The first was simply from the fact that there were patients in Manitoba who required pediatric cardiac surgery. There was also pressure from Cardiology and Surgery, departments that wished to see a faster return to full service. Youngson testified:

> I think my sense was that there was pressure from somewhere higher up. I always felt there was other meetings going on, of course, that I wasn't a part of. You know, other meetings with department heads and so forth that were going on behind closed doors. That was just my sense, you know, I don't have any facts to back that up, I just had that feeling all the time that that was going on. (Evidence, page 8,565)

On this point, Odim testified:

> Certainly at some point in evolution during the Committee there was a sense from Dr. Unruh and Dr. Blanchard of a lack of understanding of what was going on in terms of why the program was stalled so to speak.
>
> Again, it was put to me by Dr. Unruh that the problems that you are dealing with are the same problems the previous surgeon had here so they were privy to things that I was not aware of. So they were surprised that we were stalling the program because, you know, what else is new, so to speak. I can't speak for anything beyond that, except that, you know, early on in the process they were a little perplexed by what was going on. (Evidence, pages 25,356–25,357)

This pressure continued to build and in early August led Wiseman to write an interim report that recommended a staged return to full services.

NURSES AND THE WISEMAN COMMITTEE

The response that McGilton received when she opposed a return to full service at the July 27 meeting gives rise to the more general question of the treatment of nurses at the Wiseman Committee.

Ullyot testified that during the first month of the committee's work Youngson raised some of her concerns about cannulation. Ullyot said Odim was critical of Youngson for raising questions about the type of cannula that Odim was using. Ullyot testified that Odim told Youngson:

> That it was his decision to decide on the cannula, that it wasn't her place to say anything about it or to criticize what he had chosen. (Evidence, page 31,382)

Youngson testified that, following a meeting that she had left early, Wiseman contacted her. He told her that after she left, Odim had made a number of critical remarks about her. Wiseman said he was going to have the matter addressed at the next meeting. Wiseman testified that in his recollection Odim had been expressing his frustration with Youngson always comparing his work with Duncan's. Wiseman testified:

> I felt it was important, because if something is bugging someone, and it seemed to be bothering him that this was, he was constantly being put against this standard, and he wasn't willing to come out and say it to her directly, because for whatever reason, I don't know what it was, you need some—I was thinking among the experts you need to call in here, you should call in a group psychiatrist. But, nevertheless, I felt that I had to convey that to her, because clearly he wanted to and didn't quite bring himself to do it. (Evidence, page 40,548)

At the following meeting, Wiseman asked Odim if he had any concerns with the nurses that he wished to have discussed. Odim said he had none. Youngson then said that she understood that Odim had some concerns with her specifically. Odim replied by saying that he was not happy with the efficiency of her ordering. He said that the needle driver that he had seen in Saskatoon had not yet arrived. Maas intervened, saying in summer deliveries get bogged down. According to Youngson's testimony:

> At that point in time, I remember Dr. Odim turned to me and said, do you really want to do cardiac surgery, Carol? And what I wanted to say was, no, not any more, but I didn't. I said, yes, I do, I still want to participate—or he said, do you still want to participate in cardiac surgery? Because at that point in time, I was so disgusted, because it was my understanding that these meetings were, that was the reason we were having these meetings, for everybody to talk about whatever problems they were having. And I was just completely disgusted that he had waited until I left a meeting, purposely in my mind waited until I left the meeting, and then proceeded to make a personal attack on me. (Evidence, pages 8,500–8,501)

Within days of this exchange, unit manager Karin Dixon, after speaking with Youngson, met with Odim. Her intent had been to arrange a meeting between herself, Odim and Youngson. However, she came back from the meeting saying that no further meeting was necessary, since Odim said he was happy with Youngson and felt that any initial problems had been resolved.

Odim testified that he did not recall asking Youngson if she had wanted to continue working in cardiac surgery. Nor did he recall her asking if he had specific problems with her. He confirmed that the meeting with Dixon had taken place. He said that this meeting took place after he had spoken to Dixon about "disorganization in the OR vis a vis Ms. Youngson." (Evidence, page 25,240) In particular, he said, this related to Youngson's instructing other nurses during the course of the operation, a practice he found distracting. Odim said he had also spoken to Youngson about the issue, and felt that there had been an improvement in this area. He testified that since the needle driver he requested had not arrived after a period of two months, he had asked Youngson to check on the order.

When she was asked if she had raised concerns over cannulation issues in any of the cases, Youngson testified that she did not believe she had done so after the May 25 meeting.

> It's very hard for me as a nurse to criticize a surgeon, especially when there are several other physicians sitting around him.
>
> Although I did know that I had their support, I still was the only nurse at these meetings; and I just found it very difficult to sort of take a stand. What I would often do is sort of follow Ann's lead. If Ann expressed concerns about a particular case, I would back her up. That's more or less what I felt my role was at that particular time, was to sort of back her up as much as I could. (Evidence, page 8,521)

Youngson testified that after one meeting ended and both Odim and Wiseman had left, Giddins asked her what was going on in the operating rooms. Youngson said that at first she resisted answering since she would be speaking behind Odim's back. But Giddins told her that what she said would be off the record. She spoke of concerns with bleeding and cannulation and described a number of cases. Youngson testified that Giddins replied in the following manner:

> Well, he said, you know, Carol, we are very lucky to have Dr. Odim, and he sort of talked about Dr. Odim's background, and he said, you know, he's not just a cardiac surgeon. He's got his Fellowship in thoracic surgery and general surgery, and I don't remember all these other fields of expertise, and very well trained. You know, he came from Boston; and, you know, this is a guy that's got—he's extremely well trained, or words to that effect. You know, he said, he's solidly backed by the Department of Surgery. They are behind him. I got the impression by that he meant the Department of Surgery and the Health Sciences Centre administration was really, you know, anxious to have things work out for Dr. Odim, that they were really backing him up. (Evidence, page 8,526)

Youngson testified that she felt that she had been warned and ought to back off. Giddins said he could not specifically recall this exchange.

Despite the team-building rhetoric that surrounded the establishment of the Wiseman Committee, the evidence suggests that the committee did not provide a forum in which nurses could comfortably state their views. This clearly had a chilling effect on what was said, thereby denying the committee access to important information.

THE ISSUES RAISED BY ODIM

Throughout the spring and summer, the main issues that Odim raised at the committee were communication, attendance at team functions such as meetings and rounds, post-operative care and the number of anaesthetists participating in the care of pediatric cardiac patients.

COMMUNICATION

He said that there were multiple levels to the communication problem.

> I felt that communication seemed to be better from the perfusion point of view, because if they didn't hear anything, they would pipe up, and they never took offense to my raising a question because I didn't hear. I didn't get the sense that other members of the team responded in that fashion. When I asked a question, I would get no answer, and it was viewed negatively and not as I just need to know what's going on and all you need to do is acknowledge. (Evidence, pages 25,066–25,067)

Odim said he felt communication with the perfusionists was better because "they seemed to have a better appreciation of the normal conduct in a cardiac operating room." (Evidence, page 25,067) On other levels, he said information on the clinical course of a patient's treatment was not communicated to every team member.

Odim also said that at times, some members of the team would interpret a question, such as "Have you turned the flow down?" as a challenge or a suggestion that the person being asked was remiss, as opposed to them being asked a simple question. As a result, he said, people might respond by saying, "Well, of course," as opposed to simply answering the question (Evidence, page 25,085). He also indicated that he had asked members of the team to be quiet. In addition, he spoke of difficulties in getting nurses in the intensive care unit to call him early in the morning to let him know how a patient had passed the night.

TEAM MEETINGS

Odim testified that following the establishment of the Wiseman Committee, he took a number of steps that were intended to improve communication. These involved establishing clinical rounds once a week and encouraging better attendance at M & M Rounds.

The clinical rounds were to be a weekly procedure for reviewing patients at the bedside. Odim said that, despite the efforts that he and Hancock had expended in trying to establish these rounds, it had not been possible to arrange a time that was convenient to all team members.

Odim also testified that other meetings that were poorly attended included the Morbidity and Mortality Rounds. He believed the Rounds presented an appropriate forum to review the cases that were being reviewed by the committee. He felt that, because team members were not attending team functions such as M & M Rounds, they did not fully grasp why certain children had died.

Odim said that rounds were poorly attended. He also testified that, since more members of the team felt that rounds did not provide an appropriate forum for critical discussion, he:

> volunteered any other type of time frame or meeting that members would like specifically for that activity, the activity of criticism. They did not take me up on offers in the evening or on the weekends and I put the ball back in their court, come to me with a time that you think will be reasonable for this. I did not get any response. (Evidence, pages 26,383–26,384)

As a result, Odim testified, he had begun to develop concerns over the level of commitment of other team members to the program.

POST-OPERATIVE CARE AND ANAESTHESIA

Odim's personal concerns about post-operative care and anaesthesia in many ways reflected his pre-existing concerns that there should be only one intensive care unit for open-heart pediatric patients and fewer anaesthetists involved in pediatric cardiac surgery.

Odim believed it was necessary to create a smaller, more concentrated team of anaesthetists. In his testimony, he spoke of the need to have anaesthetists who had one hundred per cent commitment to the program. At times he seemed to be speaking of time commitment and the need for anaesthetists to spend more time on pediatric cardiac cases and less time on other work. He also seemed to be implying that some of the anaesthetists were not taking responsibility for the program. His repeated references to the failure of the anaesthetists to respond to his attempts to have them attend post-operative and M & M Rounds suggest that he was of the view that they did not have a sense of ownership about the program.

ODIM RESPONDS TO CONCERNS ABOUT CANNULATION

Odim also testified that he did not think Youngson's concerns about cannulas and cannulation were justified. He seemed to suggest that the problem lay with the nurses.

> They did not appear to have the cannulas that I wanted because initially I would ask for straight cannulas and I was being provided with angled cannulas and I would say well, I want to try a straight cannula and so they didn't feel that they had a large number of cannulas that I preferred. (Evidence, page 25,109)

Odim also felt that he did not have any particular problems cannulating and that the comments of others who said they had observed problems were not valid.

THE CASE OF SHALYNN PILLER

ISSUES

Shalynn Piller died on August 3, 1994, three days after undergoing surgery for aortic coarctation. This case gave rise to the following questions:

- Were Shalynn's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should the program have undertaken this operation at a time when neonates were supposed to be sent out of the province?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Shalynn Piller was born at Carman Memorial Hospital on July 20, 1994. The firstborn child of Ken and Sharon Piller, Shalynn had a normal delivery at full term, without complications. However, Sharon had undergone three ultrasound examinations, all after 32 weeks gestation, because of concerns about the small size of the fetus. At birth, however, Shalynn was considered a healthy baby, and was discharged home with her mother on the third day.

On July 30, Shalynn's parents took her to see their family physician, Dr. M. Omichinski, because Shalynn was having problems with feeding and had had episodes of irregular breathing. Shalynn was not cyanotic, but her respiratory and heart rates were rapid. She was taken to the Carman Hospital for further examination and tests. A heart murmur was heard on examination, and a chest X-ray showed an enlarged heart.

Shalynn was immediately transferred to Winnipeg, where at 1330 hours that same day, she was admitted to the Children's Hospital. On examination, she was found to have a loud murmur, an enlarged liver and decreased femoral pulses. The decreased femoral pulses were a sign of poor blood supply to the lower part of the body.

Echocardiography showed:

- two muscular ventricular septal defects, one of which was large (only one was found after Shalynn's death)
- a patent foramen ovale or an atrial septal defect with bi-directional shunting
- moderate tricuspid valve regurgitation
- a bicuspid aortic valve
- mild sub-aortic stenosis
- a significant aortic coarctation.

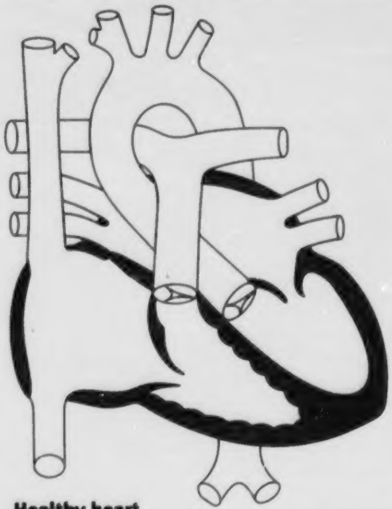
The aortic coarctation was very narrow; as a result the aorta was obstructed. The ductus arteriosus had closed, as it does in most children during the first ten days of life. However, the ductus had been the channel for blood flow to the lower body because the normal channel, the aorta, was severely narrowed. Shalynn had begun to experience her difficulties with the closing of the ductus. This had left her with marked reduction in blood flow to the lower part of her body.

Shalynn also had an abnormality in her tricuspid valve, described as Ebstein's anomaly or malformation. Odim testified that:

> That's a spectrum of abnormalities of the valve which can present, at worse, with the two or three leaflets, that is the septal or posterior leaflet of the tricuspid valve being offset, downwardly displaced into that right pump, and the remaining anterior leaflet of the right tricuspid valve being a huge billowing sail-like leaflet. Those babies that present at that extreme have a significantly high mortality rate, approaching 80 percent as neonates. (Evidence, pages 25,269–25,270)

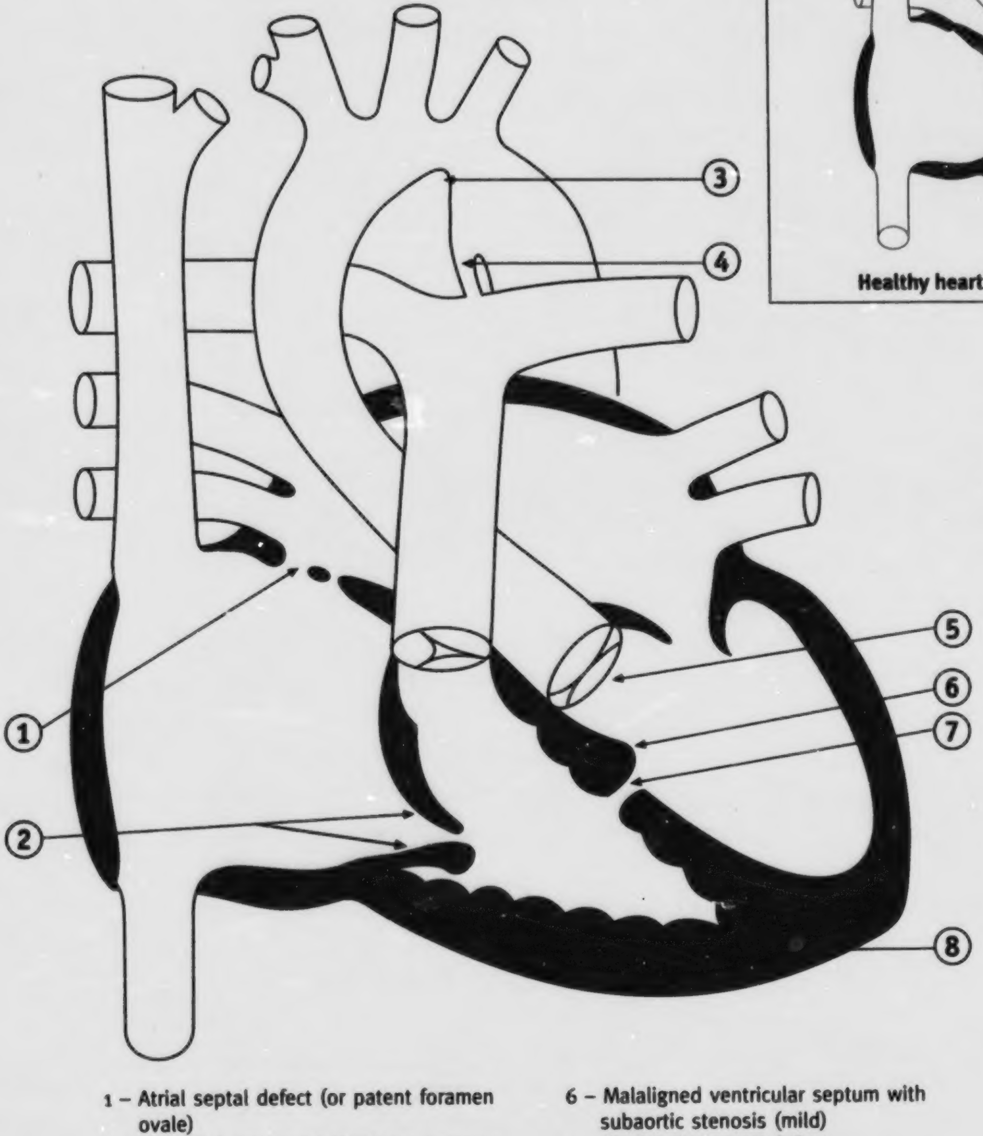
Valves with this anomaly tend to leak, allowing blood to flow back into the right atrium and causing it to swell in size.

Shalynn was treated with prostaglandin in an attempt to reopen the ductus arteriosus and restore blood flow to the lower part of her body. As Giddins explained in his testimony:



Healthy heart

Diagram 7.3 Shalynn Piller – pre-operative heart



1 – Atrial septal defect (or patent foramen ovale)
2 – Tricuspid valve with Ebstein's anomaly
3 – Aortic coarctation
4 – Patent ductus arteriosus
5 – Bicuspid aortic valve
6 – Malaligned ventricular septum with subaortic stenosis (mild)
7 – Ventricular septal defect (Although two were diagnosed, only one was found post-mortem)
8 – Right ventricular hypertrophy

> In situations where there is a narrowing of the aorta, or coarctation of the aorta, opening of the ductus tube not only provides a means for blood to bypass the narrowing, it also has a general opening up effect on the entire region of the aortic narrowing. (Evidence, page 3,923)

Shalynn was admitted to the NICU at 1400 hours. The admitting nurse noted that Shalynn appeared pale and mottled and her limbs were cool to touch, another sign of poor lower body circulation. The doctors also concluded that Shalynn was in congestive heart failure, and started treatment with the diuretic Lasix.

THE DECISION TO OPERATE

After seeing Shalynn that evening, Ward wrote "COA repair [coarctation of the aorta]/PAB [pulmonary artery banding] is believed the best option." (Exhibit 10, page PIL 37) On July 31, he wrote in her chart that he had discussed the case with Giddins and Odim. The three agreed that at that time the best surgical strategy would be to avoid the inside of the heart and place a band on the pulmonary artery to control the amount of blood flowing to the lungs. Banding narrows the artery and prevents the lung from being flooded. The band thus reduces the effect of the holes in the heart, which would have to be addressed by a subsequent operation.

CONSENT

Ward and Dr. R. Savani outlined Shalynn's condition to her parents. When Sharon Piller was told that her daughter needed heart surgery, she thought this meant she would have to go to Toronto. However, Savani told her that Odim could do the operation in Winnipeg. Sharon Piller testified that Savani told her that Odim was from the United States and implied that this was a sign of his qualifications. She testified that Ward also spoke highly of Odim's qualifications.

Odim spoke with the parents about Shalynn's difficulties on Friday evening. Sharon Piller testified that Odim told her Shalynn's chances of recovery were 92 per cent. Odim testified that he could not recall providing the parents with a specific estimate of the degree of risk involved in the case. He did tell them that further surgery would likely be needed to correct other defects. He did not tell them of the reduction in the capacity of the Winnipeg program or of any of the problems the program had experienced.

Odim and the Pillers also spoke the following day, July 31. In Shalynn's chart Odim wrote, "In view of multiple VSDs a staged biventricular approach is preferable: aortic coarctectomy and PA band via left thoracotomy. I have discussed the attendant risks and the family appears to understand and give their verbal and written consent for operation tomorrow." (Exhibit 10, page PIL 38)

In a letter to Omichinski, Odim explained that because Shalynn had multiple ventricular septal defects, he felt that a complete repair in one operation would be an unreasonable goal. He hoped with time that some of the smaller VSDs would close on their own. At that point, further surgery to close the remaining VSDs and remove the pulmonary artery band would then take place.

In his testimony, Giddins indicated that he believed Shalynn's was a low-risk case. Because it was closed rather than open-heart surgery, he also said it fell within the Wiseman Committee parameters for permissible surgery in that period. Giddins testified:

> The Wiseman committee referred to low risk open, and did not specifically get into issues of grading closed procedures, because closed procedures are a category different from open. And there had been no difficulties with any closed procedures up until that time, so this case fit in. (Evidence, page 3,925)

Because the committee's records were not well kept, it is risky to make categorical statements about what the committee did and did not approve. However, at the May 18 meeting, it was agreed that major neonatal anomalies would be transferred to Saskatoon. Shalynn Piller's case fit the classification of a major neonatal anomaly. According to the consulting witnesses who appeared before this Inquest, hers was not a low-risk condition. In their report, Duncan and Cornel wrote, "VSD and coarctation remains a condition with a relatively high risk. The addition of sub-aortic stenosis produces the potential for obstruction to both outlets – [the right side from the band and the left side from the sub-aortic stenosis], which is not a well tolerated phenomenon." (Exhibit 354, page 9) In his testimony, Duncan stated that there were major risk factors in the operation (Evidence, pages 41,619–41,620). This leads to the conclusion that the operation should not have been performed in Winnipeg.

PRE-OPERATIVE STATUS

The night before surgery, Shalynn's condition remained stable. Her white blood count was elevated and she continued to receive antibiotics. She also continued to receive medication intended to open her ductus arteriosus. However, there is no evidence that the ductus reopened. Despite receiving sedatives, Shalynn was irritable on handling. At times, she had difficulty breathing, although her air entry remained clear and her oxygen saturation level high. Her extremities remained cool to the touch and her skin colour was pale and mottled. Odim noted that her kidney function was normal, with adequate urine output. She did not have any chemical imbalances.

THE OPERATION—AUGUST 1

On August 1, Shalynn underwent an aortic coarctectomy with a primary end-to-end anastomosis. In a coarctectomy, the coarctated or narrowed section of the aorta is removed. In what is referred to as a primary end-to-end anastomosis, the remaining sections of the aorta are reconnected. Odim also permanently closed the ductus. Finally, he placed a band around the pulmonary artery. Once this band was in place, Shalynn's blood pressure started to go up, indicating that more blood was going to her body.

The operating team is set out in the accompanying table.

TABLE 7.3: Persons involved in the operation on Shalynn Piller, August 1, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	N. McEacheran (Resident)
Anaesthetist	H. Reimer
Scrub nurse	M. Wasney
Circulating nurse	E. Frederickson

TABLE: 7.4 Length of phases of the operation on Shalynn Piller, August 1, 1994

Phase of the operation	*Time taken*
Induction	1 hour 40 minutes
Aortic cross-clamp	25 minutes
Total surgical time	2 hours 30 minutes
Total operating-room time	4 hours 20 minutes

The total induction time was one hour and forty minutes. The total surgical time, from beginning the incision to closure of the incision, was two hours and thirty minutes. The total aortic cross-clamp time was twenty-five minutes. There was no bypass time, as the operation was closed heart surgery.

Shalynn had several episodes of supraventricular tachycardia (SVT, an abnormally fast heart rhythm originating from the atria) during manipulation of the heart. This abnormal rhythm resolved spontaneously. The operation was uneventful, and she was transferred to the NICU in stable condition at 1300 hours.

In his report, Cornel wrote:

> The surgery was properly performed and followed the correct decision path. The combination of atrial septal defect, ventricular septal defect, Ebstein's malformation and coarctation is one I have encountered in the past and it is extremely difficult to manage. I do not believe that an attempt to repair all of the lesions would have been more likely to succeed. (Exhibit 353, page 43)

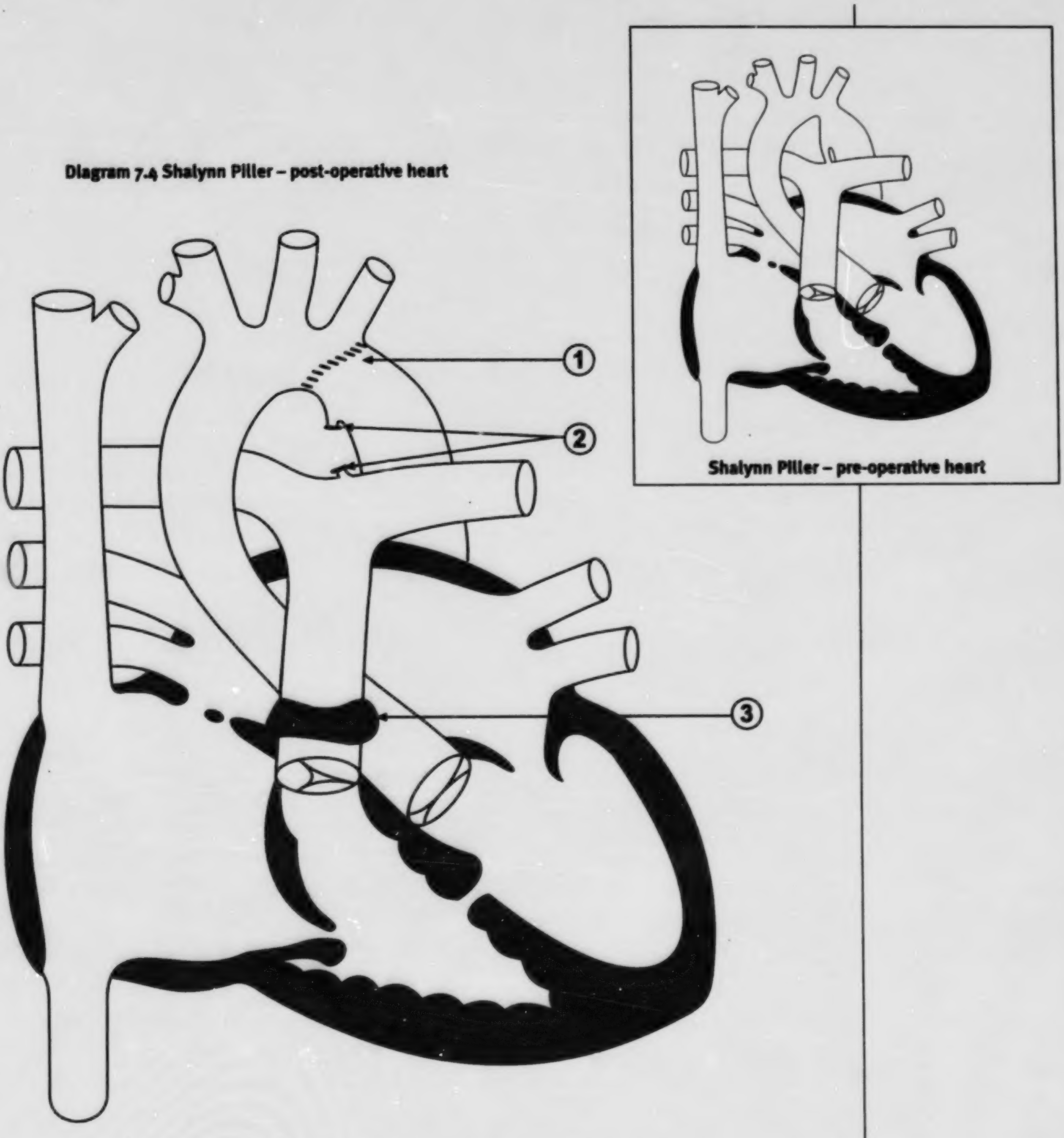
The Pillers had been at the HSC throughout the time of the procedure. At the end of surgery, Odim spoke with them and told them the operation had been successful. The Pillers stayed with their daughter until 2030 hours that evening.

POST-OPERATIVE COURSE

When Shalynn was admitted to the NICU after the operation, she was observed to have warm skin, good pulses in the lower part of her body and satisfactory urine output. Her condition remained stable until that evening.

At 2300 hours, Shalynn became extremely agitated and increasingly cyanotic. She immediately developed a slow heart rate that was unresponsive to the administration of atropine.

Diagram 7.4 Shalynn Piller – post-operative heart



Shalynn Piller – pre-operative heart

1 – Coarctation repair of aortic arch by end-to-end anastomosis
2 – Ligation and division of patent ductus arteriosius
3 – Pulmonary artery band

At 2311 hours she went into cardiac arrest. Closed chest compressions (external cardiac massage) were begun and continued intermittently over the next hour and a quarter, until 0025 hours. She was given multiple doses of atropine and epinephrine, without return of effective cardiac output. She was found to be acidotic and was treated with sodium bicarbonate.

Odim and Shalynn's parents were called to the hospital. Odim testified:

> I came in promptly into the intensive care unit to lend assistance, and discovered that, indeed, she essentially had no blood pressure or pulse without chest compressors, despite the fact of having a rate and a rhythm. (Evidence, pages 25,287–25,288)

As resuscitation continued, Odim and Ward (who had also been called to the NICU) conducted tests in an effort to determine the cause of Shalynn's deterioration. Odim thought that there might be some bleeding around the heart. As a result, he inserted a needle into the pericardium in the hope of draining off any blood that might be compressing the heart (a condition known as cardiac tamponade).

An echocardiogram performed at 0130 hours, August 2, also ruled out the presence of any fluid around the heart (or pericardial effusion, a condition similar to tamponade, but not as serious). The echocardiogram showed that the left ventricle was pumping.

A chest X-ray showed that Shalynn's lungs were clear and her heart was decreasing in size (a sign that the heart's previous swelling was lessening), and indicated the absence of a pneumothorax. (This is a condition in which air accumulates in the space outside one of the lungs, the pleural cavity, compressing the underlying lung, which may then collapse.) The tests also indicated that there was no problem with the surgical repair of Shalynn's heart. After conducting these tests, the doctors still had not found the cause of her deterioration.

Shalynn was given an intravenous infusion of isoproterenol (Isuprel) for approximately thirty minutes, to increase her heart rate and her heart's ability to contract. In addition, she was given an infusion of epinephrine, and continued to receive an infusion of dopamine. Eventually her heart rhythm and blood pressure became normal.

Between 0500 and 0600 hours, Shalynn's blood pressure started to become unstable again. At 0600 hours, she once more appeared agitated and discoloured. Her blood pressure suddenly dropped, and she again needed external cardiac massage, from 0612 to 0635 hours. She was given maximum doses of inotropic drugs (epinephrine and dopamine infusions). An echocardiogram at 0900 hours showed the performance of her left ventricle to be worsening.

There were also serious concerns about the impact that the lengthy period of resuscitation had had on Shalynn. A neurologist, Dr. J. D. Reggin, was consulted. He found that her pupils were fixed and dilated, an indication that she might have suffered brain damage. Her skin was mottled, and the blood flow to her arms and legs was poor. An electroencephalogram (EEG) was done at 0930 hours. The results showed that Shalynn was having brain seizures, for which she was given phenobarbital, to reduce the seizures. The EEG was deemed markedly abnormal, indicating acute brain damage caused by lack of oxygen. In addition, Shalynn was having other major problems, with kidney failure and coagulopathy.

At 1625 hours on August 2, the NICU staff and Odim reviewed Shalynn's condition. They were still hopeful but made a recommendation not to resuscitate her if she suffered another cardiac arrest. They discussed their recommendation with Shalynn's parents, and received their agreement.

The next day, another EEG was performed. The results indicated serious brain damage. According to Reggin, Shalynn would have had a major neurological handicap if she survived. Odim met with the parents and grandparents to discuss Shalynn's condition and prognosis. The family agreed with the decision to stop treatment, and at 1825 hours, Shalynn died in her mother's arms.

POST-MORTEM FINDINGS

Dr. Susan Phillips conducted an autopsy on August 5, 1994. She identified the cardiac surgical repairs as being intact. The right ventricle was dilated and hypertrophied, with widespread myocardial necrosis. The left ventricle was also hypertrophied, with papillary muscle necrosis. The pathologist suggested that the myocardial necrosis occurred after the cardiac arrest. The autopsy provided no explanation as to why Shalynn's condition deteriorated following surgery.

FINDINGS

As noted above, this case gave rise to the following questions.

- Were Shalynn's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should the program have undertaken this operation at a time when neonates were supposed to be sent out of the province?
- What was the cause of death and was it preventable?

Were Shalynn's parents provided with sufficient information to allow them to give informed consent to the procedure?

- **Finding**

Odim's credentials were overstated to the family. The family was not told of the slowdown in the program; nor were they told of the problems that the program had experienced. Additionally, the family was not told that the program was not to do major neonatal anomalies such as their daughter had. The degree of risk presented by their daughter was not properly communicated to them. The evidence tends to suggest that Shalynn's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Should the program have undertaken this operation at a time when neonates were supposed to be sent out of the province?

- **Finding**

The Wiseman Committee's May 18 decision was that neonates with major anomalies would be transferred to Saskatoon for operation. Shalynn should have been referred out of province instead of the team attempting her operation in the summer of 1994. The slowdown on May 17

had been initiated because there were concerns about the team's ability to manage high-risk cases. By definition, emergency operations in neonates were to be treated as high-risk. The evidence suggests that this case should have been referred out of province.

What was the cause of death and was it preventable?

- Finding

None of the medical witnesses were able to offer a definitive explanation as to what happened to cause Shalynn's death. In their joint report, Duncan and Cornel wrote that "The etiology causing the death of this child is not clearly delineated." (Exhibit 354, page 9) Dr. Walter Duncan testified that he believed the banding might have increased Shalynn's sub-aortic stenosis, by obstructing the aortic outlets and by reducing the shunt. This made the sub-aortic area smaller and thus increased pressures on it. In addition, there would be an increase in the amount of blood leaking through the tricuspid valve. As the obstruction worsened, Shalynn's cardiac output fell. However, Duncan did not take any issue with the surgical approach that was taken in this case.

It is not possible, therefore, to say with any degree of certainty what the cause of death was, nor whether the death was preventable.

PRESSURE BUILDS FOR A RETURN TO FULL SERVICE

Pressure was continuing to build for a return to full service. Ullyot testified that in either late July or early August, Craig asked McNeill and Ullyot why the program had not returned to full operation. Ullyot said Craig implied that he had been told that she and McNeill were the main obstacles to a return to full service. Ullyot told Craig that the committee had not yet reached any conclusions or even developed a report.

On August 5, Craig wrote to Bowman, the acting head of pediatrics, suggesting that he meet with Blanchard and Craig in late August or early September to discuss the Wiseman Committee's work. Craig wrote:

> One issue which has emerged is apparent uncertainty about the program objectives. Specifically, there does not appear to be agreement as to whether the program, when fully operational, should be attempting to provide surgical care for all [underlining in original] patients or whether a small number of very complex surgical problems should continue to be referred out. (Exhibit 19, Document 246)

Before any such meeting was held, it was announced that Dr. Brian Postl would take over the position of head of pediatrics and child health in mid-September. As a result, Blanchard and Craig did not meet with Bowman.

However, shortly after the August 5 memorandum was written, Wiseman prepared and presented his committee's interim report. In correspondence to Craig on August 23, Blanchard stated that the interim report was written "apparently on the repeated insistence of the involved Anaesthetists." (Exhibit 19, Document 248) In fact, the anaesthetists had not been insisting that the committee write a report in late

July—they did not believe enough work had been done to justify writing one. However, Ullyot testified that she believed that the report was drafted in response to her and McNeill's opposition to moving on to higher-risk cases before the committee had filed a report.

THE AUGUST 10 COMMITTEE MEETING

At the August 10, 1994 meeting of the committee, four matters dominated the agenda. The first was the case of a young patient with tricuspid atresia. The second was the question of where post-operative care of the pediatric cardiac patients was to occur. The third was a discussion over whether or not to proceed with a specific patient. The fourth was a proposed interim report prepared by Wiseman. Perhaps the most significant recommendation in that report was a recommendation to move to doing cases of medium risk.

Present at this meeting were Wiseman, Giddins, McNeill, Odim, Ullyot, Youngson and Seshia.

THE TRICUSPID ATRESIA CASE

The discussion involving the child with tricuspid atresia focused on the fact that the child had to be returned to the operating room to have a central shunt re-done. The notes of the discussion conclude with this comment:

> Some issues were discussed related to the ability to predict the response to the Glenn shunt and it was felt that this was essentially not possible. The issue of returning a child to the unit with significant bleeding per chest tube was also discussed. (Exhibit 20, Document 278 G)

The child subsequently recovered.

POST-OPERATIVE CARE

This was followed by a discussion of the location for the post-operative care of neonates. Dr. Molly Seshia, head of the NICU, was present for this discussion. She was a strong advocate for the position that newborn children had a unique set of problems that did not lend themselves easily to the same care as was provided to older children and to adults. She had long felt that such children should be cared for in the Nursery, as the NICU was called.

The view expressed by Odim and others was that there were not enough pediatric cardiac surgical cases involving neonates for the NICU staff to gain sufficient experience in dealing with the complications that they presented. Seshia was asked to discuss with her staff the possibility of developing a system in which neonates who had undergone open-heart surgery would be handled by the PICU, while the NICU would handle neonates who underwent closed procedures. Although not convinced that there was a problem with the way that matters were being handled, Seshia agreed.

FORTHCOMING CASES

The meeting also dealt with forthcoming cases. The minutes stated that:

> The Committee agreed in principle to continue to recommend that the Cardiac Surgical Program continue with cases at the intermediate level of complexity and/or risk. It was strongly recommended that cases not [underlined in original] be vetted at the level of the Committee. In spite of this, a specific case was indeed discussed. This was the case of a patient with an aortico-pulmonary window and an interrupted aortic arch who would require a circulatory arrest procedure which is essentially extra-vascular. It was the consensus of the Committee that this case represented the high risk end of the spectrum and that at the present time this be deferred. (Exhibit 20, Document 278G)

Giddins and Odim argued in favour of undertaking this operation and were opposed by McNeill. She believed that undertaking a high-risk case violated the decision to move slowly to doing moderate-risk cases. McNeill testified that Odim and Giddins felt that the program was losing the opportunity to undertake an 'interesting' case. By 'interesting', McNeill said, she understood Giddins and Odim to mean one that would be challenging to the team and develop its skills.

The minutes state that it was decided that the committee would continue to discuss cases that had been performed and monitor the cardiac team. Meetings were to be every two weeks rather than weekly. It was further agreed that in one month's time, at the September 7 meeting, consideration would be given to moving the program to full activity.

THE DRAFT INTERIM REPORT

The draft interim report was presented to the committee members near the end of the August 10, 1994 meeting. The minutes of the meeting state:

> The Interim Report which had been compiled by the Chairman was presented to the Committee and discussed briefly. It was the general consensus that this report was representative of the Committee's position at the present time. (Exhibit 20, Document 278G)

Wiseman prepared the report on his own initiative. He testified that at the meeting before its presentation to the committee, there had been some discussion to the effect that the committee ought to be reporting back to the three department heads. The key recommendation of the report was that the program be returned to full service in a staged manner.

By the time the report was prepared, the committee had met ten times. All but one of the open-heart cases had been reviewed. According to the report:

> As a result of the frank and open discussion which occurred a large number of problems [sic] areas were discovered and specific recommendations were made to improve the overall function of the team. Areas where problems appeared to arise included many items relating to team communication. A significant amount of discussion was devoted to improved communication between nursing, surgery, anaesthesiology, and bypass technology. It was felt that this frank discussion resulting [sic] in paving the way for a much improved communication in the future. (Exhibit 20, Document 278F)

In addition, a large number of technical details concerning the intra-operative and peri-operative management of individual patients were discussed and solutions were recommended. Some of the specific areas where changes were recommended included:

> 1. The effective use of invasive monitoring lines so as to satisfy the requirement of both anesthesiology and to meet the needs for postoperative monitoring.
> 2. Specific technical details concerning team communication relating to the going on cardiopulmonary bypass and coming off cardiopulmonary bypass.
> 3. Methodology and communication concerning the administration of anti-coagulation agents and agents for reversal of anticoagulation.
> 4. Details relating to transfer of patients from operating room to Intensive Care Unit and with respect to this the timing of a postoperative radiogram.
> 5. Details concerning the use of cardio-plegia solutions.
> 6. Specific recommendations concerning the timing and ordering of blood products for use at the conclusion of cardiopulmonary bypass. Products to be ordered from the Red Cross for availability immediately coming off of bypass.
> 7. The recognition that the operating room assistant is a major component to the smooth and safe conduct of the surgical procedure. A group of such assistants familiar with the Children's Hospital personnel and operating theatre is to be gradually developed.
> 8. The need for an operating room call-back system in the event of re-operation taking place in the Intensive Care Unit. As well the need for instrumentation for re-operation under emergency circumstances in the Intensive Care Unit.
> 9. The need to recognize that specific cases of greater complexity be not be [sic] undertaken during the early experience of the Program. It was the consensus of the Committee that the early experience included cases of an order of complexity which exceeded the program maturity at its onset. (Exhibit 20, Document 278F)

The report also stated that, by continuing to undertake straightforward cases during the period of the review, the team was able to "work together to gain confidence and during this period of time, significant success was met." (Exhibit 20, Document 278F)

This listing is impressive for what it does not deal with, namely the program's morbidity and mortality. There is no assessment of the program's mortality rate. Nor is there a discussion of the specific issues that led to mortality or morbidity. Soder, one of the consulting witnesses who appeared before this Inquest, cited surgical factors as playing a role in the deaths of four children during the period under review. Other consulting witnesses raised serious questions about the length of surgery and whether or not repairs were properly done. None of these questions were addressed by the report, which was the committee's only report before the program went back to full service.

Most of the issues on the list of matters discussed were of peripheral concern to the anaesthetists, who had called for the slowdown, and to the nurses who had enthusiastically supported the slowdown. The final point, number nine, flirts with these issues when it states that cases at the outset exceeded the program's maturity.

The report lacks concrete recommendations and is maddeningly vague. For example, it is unclear from point 9 as to whether or not the committee had concluded that the team was, in August 1994, sufficiently mature to handle those cases that had exceeded its maturity a few months earlier.

The draft report concluded with the following statement:

> It was generally agreed that the Program proceed with cases generally falling into the low and medium risk category, and that at the present time, cases in the high-risk category be deferred. This is recommended to continue for a period of 4 to 6 months. (Exhibit 20, Document 278F)

While this paragraph appears to indicate that the program slowdown would continue for a considerable period of time, the statement in fact opened the way to a rapid return to full service. In the final draft of the interim report, the last sentence reads, "This is recommended to continue for a period of 3 to 6 weeks." (Exhibit 19, Document 246) McNeill testified that the committee had agreed that four to six months was too long a time, although she thought the period was going to be shortened to six to eight weeks, not three to six weeks.

On the question of the pace at which the program would be accelerated, the draft interim report read as follows:

> After considerable Team discussion and with a [sic] some degree of trepidation it was recommended that the overall approach to the Cardiac Program occur with the development of a staging system based upon complexity and risk involved with individual cases. (Exhibit 20, Document 278F)

In the final copy of the report, the word "trepidation" was replaced with the word "reservations" (Exhibit 19, Document 246).

This clearly reflects the lack of consensus over returning to full service. The report stated that patients could be considered as either low, medium or high-risk. It was only at this point in the committee's history, when the program was on the point of returning to full service, that it set about defining risk categories. Low-risk patients included many of the closed procedures, as well as simple open-heart procedures with short bypass times. These included atrial septal defects and Glenn shunts. Moderate-risk cases included ventricular septal defects, Tetralogys and incomplete atrioventricular canals, and "patients undergoing primary repair of anomalies which occur with a reasonable frequency and are not usually associated with high mortality." (Exhibit 20, Document 278F) The high-risk cases included both complex neonatal repairs and reoperations on patients with previous palliative repairs. With such a list developed, it was agreed that cases would not be vetted through the committee.

McNeill, Ullyot and Youngson were somewhat taken aback by the presentation of Wiseman's draft report. They felt it was presented without any prior discussion and did not represent their views. Yet it became adopted as the committee's interim report, apparently with their approval. This gives rise to some questions about decision-making in the committee.

In her testimony, McNeill gave this description of how consensus was determined in the committee:

> It was sort of, we would all discuss something, and then perhaps one or two people would reiterate the idea or express sort of an encapsulation of what we had just said. And somebody may have been arguing against it or critical of it, or having a different opinion, but at the point that the idea is summarized, if they then don't say anything, that summary becomes the consensus. (Evidence, page 13,312)

In many instances, McNeill said she felt that statements became consensus not because everyone agreed with them, but because they had stopped arguing against them and were simply prepared to let them stand.

Youngson, McNeill and Ullyot had felt almost from the outset that the committee process was not adequately addressing the concerns they had about the program. They had felt that the major issue was the ability of the surgeon, but had not been able to raise that concern about his abilities very strongly because of their lack of surgical expertise. Youngson recalled the manner in which McGilton's questioning of the suturing of the eustachian valve in the KZ case had brought about such a strong reaction from both Odim and Giddins and how McGilton's views had been dismissed as coming only from a nurse.

McNeill had also felt all along that Giddins, Odim and, to a certain extent, Wiseman had viewed her as being obstructionist and unco-operative in her assessment of the levels of care the program was able to provide for cardiac patients. She, too, felt that even though she was a trained anaesthetist, she was unable to argue forcefully that there were valid surgical issues that had not been addressed during the process up to that time.

She had felt that the committee suffered from a lack of members with pediatric cardiac surgical experience who could assess and comment on any of the surgical issues that were raised or needed raising. At the meetings, whenever a surgical matter had been raised, she felt that Odim's view was invariably accepted and that there was little room for dissent, especially since no one at the table could match Odim's credentials in matters of pediatric cardiac surgery.

Youngson, Ullyot and McNeill were not confident at all that the program was ready to proceed to operating on all children. However, they were all hesitant to speak out against the contents of the interim report, since their true concern was their lack of confidence in the surgeon—a position they felt unable to express at the committee or to articulate convincingly.

McNeill testified:

> I think that we didn't sometimes actually speak clearly, forthrightly and critically about incidents that we felt were—that had occurred or we had concerns about.
>
> ***Question:*** Why not? Why not?
>
> ***McNeill:*** On my part, I think that, or I know that it was a combination of feeling that there was expectations of me to be part of a healing process almost, if you will. There was a definite intent that was reiterated by the people who set up the committee and by department heads that this should be a mechanism for improving the general tenor of relationships.
>
> So with that sort of background and that message being delivered to me, I felt that if I had an issue that I wanted to discuss, I should try to do it in as least a confrontational manner as possible, and if possible, to avoid being directly and personally critical and try to address the issue from a more unbiased and perhaps from a farther back perspective. So I had the sense of expectation of my behavior, if you will.
>
> I think another factor that played a large role in it is, it is difficult to confront somebody, it is difficult to say, I think you did or did not do this. Even in a forum that was, you know, set up with that sort of a purpose in it, it isn't always easy to do. And I know I avoided doing it at times for those reasons. (Evidence, pages 13,296–13,297)

Ullyot testified that during August, she and McNeill had concluded that a return to high-risk cases was almost inevitable.

> I think we had just sort of come to the conclusion that if the push was on to increase the complexity that we weren't going to have a real problem with that in managing the cases, that we just perhaps should just let this start to happen. Even though we weren't particularly happy about it, even though we had objected to it occurring, that we weren't the only people in that committee, we weren't the only people deciding that the cases should proceed and that we should start doing medium risk

> cases, and that we had a responsibility to object, but that if the committee as a whole decided that's what we would be doing that we would go along with that. (Evidence, page 31,413)

Ullyot testified that she did not believe the minutes of the August 10 meeting were accurate in their statement that all the committee members had accepted the report. She said that at the August 10 meeting, she indicated her concern that the report "did not address the fundamental question of whether the mortality was acceptable." (Evidence, page 31,395) She was told that the other members of the committee were comfortable with going ahead and that the mortality and morbidity rates were acceptable, based on the reviews of the individual cases.

Odim testified that the committee discussion did not always appear to be as full and frank as the interim report suggested. While he said that the summer results had been encouraging, he testified that:

> There was still certain combinations of players created the wrong chemistry and there was still some attitudinal things that still existed, but I don't think they really had any bearing on, you know, what we had to do as professionals, but my personal sense was that there was still some issues that really weren't quite resolved and I don't know whether everything was frank and open. (Evidence, page 25,325)

The people he was referring to were Youngson, Hinam, Swartz and McNeill. In short, while Odim wished to see the program return to full strength, he was developing reservations about the team's capabilities. This was reflected in his ambivalent testimony on the report's conclusion that the team had taken on cases that exceeded its maturity. At one point he rejected the conclusion, while at another point he accepted it, stating that the team was capable of performing the cases that it undertook upon startup; however, he also felt that there were problems with the team's maturity.

While Odim had a number of concerns about the chemistry of the operating-room team members and about post-operative care, he did not believe that these problems needed to be fully addressed before moving back to full service. He believed that, at that point, the program could provide acceptable care, as opposed to what he called optimal care.

In many ways, it appears that point number 9 (the statement that the team had taken on cases that exceeded its maturity) was, in large measure, offered as an appeasement to the program's critics. Odim and Giddins accepted that they had to agree with the point, if they wished to see the program return to full service. This point was made apparent when Wiseman was asked who, during the committee's work, had identified cases that were of an order of complexity greater than the team's maturity. In response, he testified:

> Well, the committee, I think it's alluded to or suggested, even the terms of reference of the committee is to kind of this gradation phenomenon, the need to sort of step back and have a look. It was very clearly meant to make recognition of this fact, that's this lucidity phenomenon. That's why this—
>
> ***Question:*** Did Dr. Odim agree that the cases at the beginning of the program had been too complex, by the time you wrote this?
>
> ***Wiseman:*** I think insofar as the proceedings of the committee led to this conclusion, yes.
>
> ***Question:*** Did Dr. Giddins agree that the cases selected at the beginning of the program were too complex?
>
> ***Wiseman:*** Again, in sort of, from a retrospective perspective, I would say yes. (Evidence, page 40,626)

It was recommended that the interim report be forwarded to the three department heads.

THE INTERIM REPORT IS DISTRIBUTED

On August 22, 1994, Wiseman sent copies of the report to Blanchard, Craig and Dr. John Bowman, the acting head of pediatrics. On August 23, Blanchard responded in a note to Wiseman:

> I have some difficulty with statements in the latter part of the report. The assignment of arbitrary risk levels as a basis for the decision regarding whether the patient should have an operation in Winnipeg makes no sense in and of itself. The mere existence of increased risk for certain categories of congenital cardiac defects should not be a criterion for acceptance or rejection of the patient for treatment in Winnipeg or elsewhere. After all of the meetings and the improved communication why is there need for a further moratorium of three to six weeks during which so-called low and medium risk patients will be acceptable for surgery in Winnipeg and higher risk patients deferred? (Exhibit 19, Document 249)

There is some merit to Blanchard's question. Why were people still reluctant to take the program to full service after a summer of team building? The fact that there was such reluctance should have caused Blanchard to question whether the program should undertake such a step without full support and confidence. However, instead of raising that concern, Blanchard went on to question why the program could not have moved to full service sooner.

Blanchard saw the use of risk categories as being artificial. He said his concerns about the levels of risk reflected a worry that the program might be attempting to improve its surgical outcome by avoiding cases it was capable of doing but that carried a higher risk. He testified:

> It wasn't clear to me, in reading the report, you know, what were the decisions they had to make now, what were the obstacles? Were we missing some equipment? Were there some problems with deciding on cases? It wasn't sort of totally clear to me just how they were going to make this decision, and what would another few weeks difference make? (Evidence, pages 36,537–36,538)

Wiseman responded to Blanchard's memorandum on September 6, with the following comments:

> With respect to the "arbitrary risk levels" and decisions regarding surgery we discussed this at length and it seems that this is the only way that the program could continue with the participation with the Department of Anesthesia. In truth, the risk levels are not quite so arbitrary. They do represent patients with low, medium and high mortality rates and it was initially stated that the program should recommence with a graduated case load, specifically with respect to case complexity. I would only add that it seems in retrospect that this was perhaps not a bad decision in view of the fact that there have been an additional 16 cases carried out since our deliberations commenced and all [underlining in original] of these patients have had a successful outcome.
>
> I believe we are on the verge of allowing this program to go forward at full capacity and at the present time the team members do appear to be gaining confidence with each other. (Exhibit 19, Document 250)

It should be again noted that this overstated, by a considerable degree, the degree of team cohesiveness that had been developed by this point. There is an even more disturbing overstatement. Wiseman stated that all the patients who had undergone surgery since the shutdown had experienced successful outcomes. By the time he wrote his response, two children who had undergone surgery in Winnipeg, Aric Baumann and Shalynn Piller, had died. Furthermore, Wiseman had been informed about these deaths by August 24. When questioned about this omission, Wiseman was not able to offer any explanation, other than to suggest that he had forgotten.

THE WISEMAN COMMITTEE
PLANS TO RETURN TO FULL SERVICE

The committee met on August 24. The case of Daniel Terziski was discussed at this meeting. According to the minutes, the discussion led to revisiting the question of the post-operative care of neonates. The committee concluded that it should recommend that all open-heart cases be sent to the PICU, as opposed to the NICU. According to the minutes, the discussion of the Terziski case ended with the following conclusions:

> The child went on to have ventilator dysfunction and proceeded relatively soon after return to the Nursery to have a cardiac arrest resulting in the need to open the chest and determine the patency of the shunt. The child expired and it was felt that there was no specific single component in the management of the patient which contributed greatest to the demise. Factors such as the prolonged arrest time were discussed, as well as the need to revise the shunt size. (Exhibit 20, Document 278 H)

Without belabouring the point, it is worth noting that the consulting witnesses to this Inquest identified a number of other serious problems with this operation. Duncan and Cornel questioned the wisdom of the team undertaking a Norwood procedure. This was also one of the cases about which Soder concluded that the

> **skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations.** (Bold in original) (Exhibit 345, page 8)

The inadequacy of the committee's approach is revealed by the extreme difference between the committee minutes and the reports prepared for this Inquest by consulting witnesses.

According to the minutes, after the discussion of a second case that was largely uneventful, the meeting turned to the cases that had taken place after the establishment of the committee.

> The overall sense was that the results of the more recent experience have been satisfactory. Small problems have been encountered however the team communication and overall conduct of procedures appears to have improved.
>
> It was further mentioned that there have been 4 cases carried out which are considered to be of an intermediate level of complexity and the results of these are also satisfactory.
>
> Two deaths were mentioned including the death of a child in the Intensive Care Unit with previous repair of an ASD and the death of a child in the Intensive Care Nursery who underwent repair of a hypoplastic aortic arch.
>
> The Team members recognize that there is significant pressure to increase the level of activity of the Cardiac Program and this of necessity will require the need to recommend in two weeks that the Program be allowed to continue at its full operating level. (Exhibit 20, Document 278 H)

It is useful to note the way that the return to full service was accelerated in the month of August. On July 27, it appears that a move to do medium-risk cases was turned down. By August 10, a report that recommends moving to full service in four to six months is accepted. According to some of the participants at the meeting, they expected the time line to be shortened in the final report. However, they did not expect it to be reduced to four to six weeks. Two weeks later, at the same meeting where the committee was informed of two deaths and reviewed the Terziski case, Wiseman informed the committee that he was recommending a return to full service in two weeks time.

The program had clearly been rushed back to full service.

Wiseman testified that when using the word 'pressure', he was referring to patient backlogs. When asked why the backlog required that the program return to full operating level, he testified:

> This was, I think, this is awkward phrasing and, again, I am guilty of it here. I think that we had sort of agreed that in two weeks we would make a decision, or at least have a plan, so he could take away something in terms of when the program would be reactivated.
>
> So that we were sort of trying to, I think, my sense was that the team was trying to posture itself to make a decision. And this was, two weeks was selected as a time to decide, to make a recommendation in two weeks whether the program was going to commence in another six months or three months or two months, so that Dr. Giddins would have some directive. (Evidence, page 40,650)

Wiseman testified that the statement in the minutes should be read as saying that in two weeks time a decision would be made about whether or not to return to full service.

THE ANAESTHETISTS AGREE TO RETURN TO FULL SERVICE

Before the September 7 meeting, at which the recommendation to return to full service was to be discussed, Ullyot met with the four pediatric cardiac anaesthetists individually and discussed their positions on returning the program to full service. They each told her that, despite their ongoing concerns about the program, and in particular the skills of the surgeon, they were prepared to return to doing high-risk cases.

McNeill testified that she had reluctantly come to the conclusion that continued resistance to allowing the program to return to full service was approaching futility, since she felt that the anaesthetists had had an opportunity to have the question of the viability of the program addressed and had not been able to get others to see the legitimacy of their concerns.

THE RETURN TO FULL SERVICE

When the committee met on September 7, it first dealt with Blanchard's comments on the interim report. The minutes concluded that the "risk level, although awkward to deal with, had assisted in resolving differences between members of the Cardiac Team." (Exhibit 20, Document 278 I) The minutes further stated that in the previous two weeks, two infants had undergone successful operations. Giddins noted that since the program had been partially suspended, three of the eleven patients who had been sent out of province had died. A survey of VCHC records indicates that, in fact, fourteen patients had been referred out of province during this period. One died within twenty-four hours of surgery, one died thirty-two days after surgery (twelve days after being initially discharged from hospital), and one died forty-one days after surgery (twenty-one days after being discharged).

> Discussion occurred concerning the impact of sending patients away from the program in Winnipeg. It was felt that these patients constitute a significant part of the overall patient population and as such the local program is considerably weakened by their transfer. (Exhibit 20, Document 278 I)

Wiseman believed that the program was weakened because a reduction in the number of complex cases affected the development of the team's skills. McNeill did not believe the program had been weakened, if by that term one meant a decline in team members' skills by sending some patients out of the province. However, she did agree that the program was not providing the services originally intended. To that extent, she agreed, the program was weakened.

The meeting then went on to discuss the program's future.

> Following discussion of this issue it was the consensus of the members of the committee that the program now continue at full capacity. Specifically, it is intended that patient selection for surgery will be the responsibility of the Cardiac Surgery and Cardiology Departments. ***It was recommended that discussion re: patients and review of patient management occur appropriately at the Friday end of month session which is intended to allow all members of the Team to participate fully***. (Bold and italicized in original) (Exhibit 20, Document 278 I)

Wiseman testified that while the surgeon and the cardiologist would be selecting patients, other team members would have input into the selection process, when the recommendations were presented at the pre-operative conference.

Finally, it was recommended that Seshia be invited to attend the committee's next meeting to discuss post-operative care issues.

McNeill testified that, in agreeing to the return to full service, she was not simply responding to pressure. She said she felt that the surgical results over the summer had been positive, as were the few moderate-risk cases that had been undertaken. She said that, while relations with Giddins and Odim were not friendly, they were civil. However, she felt that the review had not accomplished all that had been hoped for.

> I know, when we went into the process we had concerns about surgical technique, or the surgical side of the patient management that I didn't feel was addressed completely through the process. Whether it could have been or not, because by the nature of what we were doing and the way we were doing it, I am not sure that we really stood much chance of necessarily answering all the questions that we had at the beginning.
>
> So, from my point of view, and also the other anaesthetists, because I spoke with them, we felt that was still a partially unresolved issue at the end of this.
>
> *Question:* I know we have been over this before, but can you clarify as to why you couldn't get at that?
>
> *McNeill:* In many ways because it came down often to non-surgeons commenting on surgical care. So, there is always, no matter, you know, how you approach it, you get to that bottom line. And there perhaps would have been a more likelihood of resolving issues if there had been a mechanism for other surgeons to examine the issue or comment. (Evidence, pages 13,371–13,372)

Wong testified that he thought it was a mistake to return to full service.

> I didn't think that we had had enough time on the lower risk cases to really develop confidence for the team in each other again, and work together. And an example like what we just talked about [Wong was referring to the suturing of the eustachian valve in the KZ case] was one of the reasons that I had concerns. (Evidence, pages 19,914–19,915)

Wong was asked why he agreed to a return to the full program when he had these reservations.

> Basically, the evidence had been presented to the administration aka the Wiseman committee and, you know, it was their judgment that it was safe to return. And it was out of our area of expertise to decide what was safe and what was unsafe, so we agreed, even though our reservations were not satisfied.

> As well, we had agreed to abide with the findings of the committee, so we were, I guess you would say we were being team players, even though we weren't happy, everybody else said it was okay, so we reluctantly agreed. (Evidence, pages 19,915–19,916)

Throughout the period when the team was doing only low-risk cases, Youngson said that while the surgical outcomes had improved, there were still ongoing problems with cannulation. When testifying about the September 7 decision, she stated:

> Well, I think we were all happy with the results over the summer for the most part. Things had gone fairly well. There had been a couple of things that had happened in the operating room, but for the most part, the outcomes had been what we had hoped for.
>
> I think anaesthesia still had some reservations about going to a full program, and so did nursing. But at this point in time, I was not prepared to voice my opinion any more at these meetings. I just was there more or less as an observer later on in the year.
>
> I really didn't feel that nursing concerns were considered important to—certainly to Dr. Odim and to Dr. Giddins. (Evidence, pages 8,572–8,573)

In this general state of dissatisfaction over the review process, the Pediatric Cardiac Surgery Program prepared to return to doing all cases.

CONCLUSION

The period from May 17 to September 7 constitutes a period during which the hospital undertook an internal review of the Pediatric Cardiac Surgery Program. That review was undertaken by a committee chaired by the director of pediatric surgery for Children's Hospital, Dr. Nathan Wiseman.

That committee suffered from a number of deficiencies from the outset. It lacked a mandate broad enough to address the issues that were being raised privately by anaesthetic and nursing staff. The committee lacked the personnel to conduct an expert assessment of the issues that were being raised. Finally, it does not appear to have developed a systematic approach to reviewing cases.

At the outset of this Inquest, the court was informed that there were no minutes for the committee. Yet, as the Inquest proceeded, minutes were in fact produced, in a piecemeal fashion. It appears, however, that there were some meetings for which there are no minutes.

Furthermore, the committee's interim report contains no assessment of the care that was given to children in the program, particularly to those children who died. The focus of the report is almost entirely on issues relating to communication and team building.

The committee did not develop any plan of action that would address the issues that had been identified. For example, there were no recommendations dealing with case selection, communication or monitoring.

At the same time, a number of cases took place during this period, VM and KZ in particular, that indicated that the issues the nurses and anaesthetists had been speaking of to their supervisors were still of considerable concern to members of the surgical team.

While McNeill and Youngson testified that they concurred with the decision to go back to full service, it is apparent from the evidence presented to this Inquest that they had very serious reservations and would have preferred not to return to full service at that time. However, the built-in failings of the committee structure left them with little option. The cases had been reviewed, and while it was stated that a consensus had been arrived at, it would be more accurate to say that a dominant view had been imposed.

COMMUNICATION

Following the February restart of the program, there had been a major breakdown in communication. Nurses had spoken to their supervisors and anaesthetists, and to their division and department heads about the concerns they held with morbidity and mortality. The nurses and anaesthetists had also taken their concerns to Wiseman, who they believed was in charge of the Pediatric Cardiac Surgery Program. Wiseman chose not to observe Odim in operation. Instead, he appears to have discounted the opinions of the nurses and anaesthetists, and adopted the view that there were no surgical issues. From the way Wiseman structured the committee review, it appears that he interpreted the nurses' and anaesthetists' views as merely reflective of poor teamwork and their inability to deal with the deaths of patients.

The structure established for the committee may have been intended to build the team, but in reality it made team building impossible because the ground rules prevented the nurses and anaesthetists from raising issues that were most important to them. They could not effectively raise the issue of surgical competence because it was outside their area of expertise and because such a line of discussion went against the committee's goal of fostering camaraderie. In addition, the assistance that the committee needed to determine if the concerns of the nurses and anaesthetists over surgical ability had any validity was lacking.

DECISION-MAKING

Decision-making by consensus can be a powerful team-building tool. However, it requires that all members of a group agree to the decisions that the group is making. This means, however, that one member of the group can effectively block a decision. Decision making by consensus, therefore, can work only if the group is truly committed to developing real consensus, each member has a full opportunity to express his or her view (and is heard) and each member agrees not to act unreasonably in blocking a decision. Additionally the members must have an opportunity to feel that something has been agreed to.

This was not the case with the Wiseman Committee. The treatment given to Youngson and McGilton made it clear that nurses' views about medical issues would not be accorded much weight. Additionally, they would clearly have gained the impression that they would not be allowed to block decisions agreed upon by doctors. Furthermore the manner in which minutes were kept and circulated—and apparently never discussed, let alone agreed to—indicates that there was no proper decision-making process.

As a result of these shortcomings, communications at the committee were not forthright; nor were decisions (as reflected by the chairperson) reflective of the true feelings of some of the committee members.

As the program returned to full service, the conflicts and concerns of the spring re-emerged. Tragically, the program continued to be plagued with serious morbidity and mortality. These conflicts and problems eventually led to the full suspension of the program and the appointment of an external review, a decision that should have been made in May 1994, rather than in December of that year.

Chapter 8

EVENTS LEADING TO THE SUSPENSION OF THE PROGRAM

SEPTEMBER 7, 1994 TO DECEMBER 23, 1994

On September 7, 1994, the Wiseman Committee determined that it was appropriate for the Pediatric Cardiac Surgery Program to resume full service, which it did for the next three and a half months. Following the deaths of five more children, however, the program was stopped, pending the institution of an external review. The program has not reopened since the suspension.

The events of that three-and-a-half-month period are described and discussed in this chapter. It should be noted that, during this period, Dr. Brian Postl assumed the position of head of pediatric services. While Postl was originally under the impression that the problems of the PCS program had been resolved, he became increasingly concerned about the program. As problems mounted, he sought more information and took steps that he had reason to believe would address problems in the program.

As opposed to the first half of 1994, many of the difficult operations that were carried out and deaths that occurred during this period involved newborns. As a result, the neonatal intensive care unit became increasingly involved in the care of children from the Pediatric Cardiac Surgery Program. Representatives of that unit played a key role in the decision to suspend the program in December 1994. At the same time, as the following text indicates, the program continued to be plagued with problems in communication and with concerns about the surgeon's technical abilities.

SEPTEMBER 7 – THE RETURN TO FULL PROGRAM

Following the September 7, 1994, Wiseman Committee meeting, the members of the pediatric cardiac surgery team prepared to return to a fully operational program. Some team members still harboured significant concerns about the program's ability to provide appropriate care for patients with heart defects of high complexity. As was the case before the original slowdown of May 17, that concern rested almost exclusively with the nurses and the anaesthetists.

Although the program had been through a hiatus in providing care for patients with complex anomalies, it was obvious that little had been learned from the experience of earlier in the year; once again, little time was spent in preparation for the return to high-risk operations.

While a number of significant issues had been identified during the committee process, none of the procedures that had been in place before May 17 were altered when the program returned to full operation in September. Case selection and preparation had been raised as a significant issue at the committee. Despite this, there was no recommendation for any additional or improved pre-operative meetings that would involve pediatric cardiac surgery team members other than the cardiologist and the surgeon.

Communication had clearly been flagged as a serious issue; yet nothing was put into place to address issues of communication on an ongoing basis. No debriefing sessions were held after difficult cases, a small step that would have gone a long way to addressing any concerns that arose intra-operatively.

The concerns expressed by the PICU and NICU staff, about procedures being performed in their units for which they were ill-prepared, had not been addressed. Preparation of the cardiac bins—which had begun as early as April—had not been completed.

The Wiseman Committee's interim report would have left the department heads, to whom it was sent, with the impression that all matters of concern had been addressed and resolved during meetings of the committee. Unfortunately, this was a false impression.

CRAIG'S MEETING WITH THE ANAESTHETISTS

Dr. Doug Craig, the head of anaesthesia, met with the pediatric cardiac anaesthetists on either September 8 or 9. Dr. Ann McNeill testified that he wanted reassurances from them that, since the program would be returning to full service, the pediatric cardiac anaesthetists would be full participants in the program. At the time of that meeting, Craig was not aware that they had individually met with Dr. Suzanne Ullyot and had agreed to work in the program when it returned to full service. According to McNeill:

> During the discussion he said something to the effect that if we were in the United States, we would be looking for jobs, or we would be out of jobs, or we might not have jobs, something like that. (Evidence, page 13,346)

Dr. Harley Wong felt intimidated by Craig's comments as to what would have happened "if they had been in the United States." Because Wong had already decided to participate fully in the Pediatric Cardiac Surgery Program once it returned to full operation, Craig's comments did not have an impact on his decision to participate. However, he indicated that the comment had a chilling effect on his view about the support that the hospital was prepared to give to the anaesthetists in the future, if they once more withdrew services.

Craig testified that his statement about the United States came from his experiences on the Board of the American Anesthesia Educational Association. He said he had learned that in the United States hospitals were running "roughshod" over anaesthetic departments that were seen to be getting out of line.

> The point I came back to was that if you don't sort of toe the line, there is a risk in the U.S. that you will lose your job, in a very abrupt way. In some context, I recall that I said that if you were in the

> United States, and I guess saying whatever they were saying and doing, whatever they were doing, that you might get fired or would get fired, if you were in the United States. So that was the context.
>
> It was never, as I heard it, converted that if you don't do something or do something that you will get fired. I never threatened to fire them, that I am aware of. (Evidence, pages 34,537–34,538)

After Craig had made his comment, McNeill told him that the section of pediatric cardiac anaesthesia had already made the decision to participate fully when the program returned to full activity.

The nature and tone of the discussion reflected the anaesthetists' lack of support for the decision to return the program to full activity. Craig recalled that there was heat generated at the meeting, although he could not recall how the discussion became so heated.

> Dr. McNeill, I know was, I guess the heat generation leader, she was the most vocal, and she was the one that called me a few days later to apologize for her tone in the meeting. And I'm not sure that was on behalf of them all or herself. Whatever it was, I accepted the apology.
>
> Dr. Heinz Reimer was unusually vocal for himself. And that is the meeting at which he, I guess in essence blurted out at some point, you know, that for a surgeon to be effective in this kind of a program, the surgeon has to be an exceptional surgeon, I remember him saying that, and that Dr. Odim is only an average surgeon, I heard him say that. The context of that, I don't recall, but I recall him saying that. (Evidence, pages 34,535–34,536)

The anaesthetists' reluctant return to the program clearly reflects the ineffectiveness of the Wiseman Committee process in addressing their concerns. While Craig's comment about what might have happened to them if they had been in the United States might not have been intended to intimidate, it could hardly have had any other effect. It seems that the message was being conveyed that the anaesthetists had been 'catered to' and while they had had their way, this was not to happen again.

It is likely that the meeting with Craig did have an impact on the anaesthetists' willingness to speak out. Five more children died before the end of the year, and although there was still cause for concern over some of the same issues that had been raised earlier in the year, the voices of the anaesthetists were much more muted. Less than a week after the program returned to full activity, another child died.

THE CASE OF MARIETESS TENA CAPILI

ISSUES

Marietess Tena Capili died on September 13, 1994, after undergoing surgery to repair a complex series of congenital heart defects.

The issues to which this case gives rise are:

- Should the operation have been performed in Winnipeg or should Marietess have been referred out of province?
- Were Marietess's parents provided with sufficient information to allow them to give informed consent to the procedure?
- What caused the superior vena cava syndrome?

- Should the surgical team have kept Marietess in the OR until the cause of the superior vena cava syndrome from which she was suffering was identified?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Marietess Tena Capili was born on December 15, 1991, at St. Boniface General Hospital to Sarah Marie Tena and Benedict Santos Capili. At birth, Marietess was diagnosed with a complex congenital heart defect. Tests showed she had:

- a double outlet right ventricle
- a hypoplastic left ventricle
- a hypoplastic mitral valve annulus (not depicted in diagram 8.1)
- a ventricular septal defect
- an atrial septal defect
- severe subpulmonary stenosis
- anomalous pulmonary venous drainage
- an interrupted inferior vena cava with azygous continuation to the right superior vena cava
- a left superior vena cava draining to the coronary sinus.

This was a very serious and complex set of heart problems. It is worth reviewing what each of these defects is and how they interacted in Marietess's case.

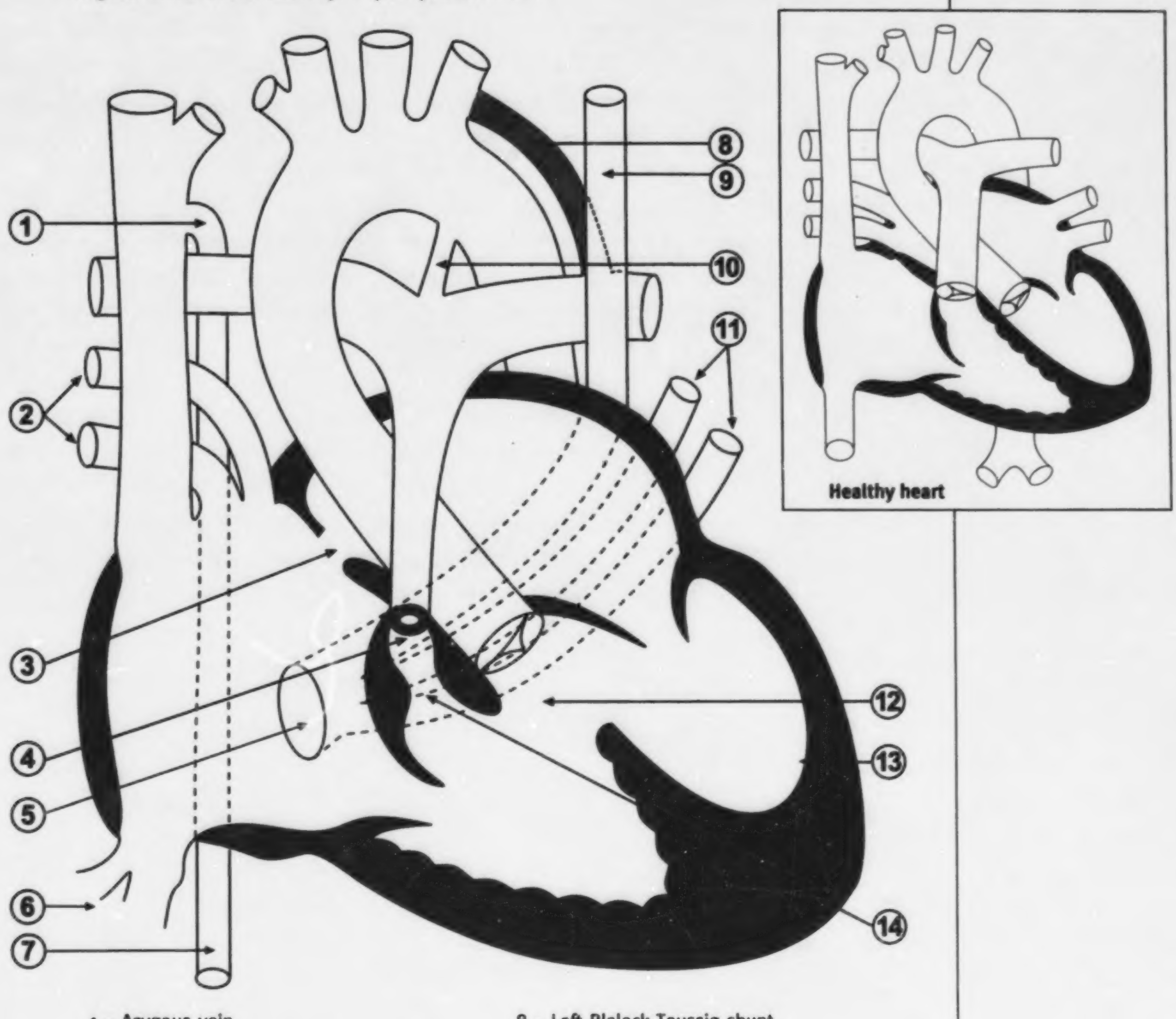
Both of the great arteries, the aorta and the pulmonary artery, arose from the right ventricle, giving the right ventricle two outlets. Because of the Double Outlet Right Ventricle (DORV), Marietess's aorta was connected to the right ventricle, rather than to the left ventricle. Her left ventricle was also underdeveloped or hypoplastic. Dr. Jonah Odim described Marietess as having a single ventricle or pump because the left ventricle was so small. Furthermore, the ring (or annulus) of the mitral valve connecting the left atrium to the left ventricle was underdeveloped.

There was a large VSD in the septal wall between the right and left ventricles, which was described as non-restrictive, in that the hole allowed free left-to-right shunting of blood. There was also an ASD in the septal wall between the left atrium and right atrium. This allowed blue blood to flow from the right atrium to the left atrium.

In fact, Marietess did not have a normal atrial structure, since there was an incomplete differentiation between the left and right atria. The lung drainage, instead of connecting to the left atrium, connected to the back of what amounted to a common atrial chamber. The right and left pulmonary veins brought oxygen-rich blood back to this common chamber, thus mixing the red blood with oxygen-poor blue blood.

There was a narrowing just before Marietess's pulmonary valve opening, increasing the resistance to blood flow from the right ventricle to the pulmonary arteries. In Marietess's case, this stenosis actually served to protect against congestion of the lungs.

Diagram 8.1 Marietess Tena Capili – pre-operative heart



1 – Azygous vein

2 – Anomalous pulmonary venous drainage (Right pulmonary veins draining to the right atrium)

3 – Atrial septal defect

4 – Bicuspid stenotic pulmonary valve

5 – Coronary sinus

6 – Hepatic veins draining to right atrium instead of to inferior vena cava

7 – Azygous continuation of inferior vena cava

8 – Left Blalock-Taussig shunt

9 – Left superior vena cava

10 – Patent ductus arteriosus

11 – Anomalous pulmonary venous drainage (Left superior vena cava draining left pulmonary veins at coronary sinus)

12 – Ventricular septal defect with overriding aorta (Double outlet right ventricle)

13 – Hypoplastic left ventricle

14 – Severe subpulmonary stenosis

Marietess's vena cava system was also quite unusual. In essence, the interrupted inferior vena cava meant that Marietess did not have an inferior vena cava. To compensate for the absence of this blood vessel, blood flow from the lower body came up behind the heart through the azygous vein. This vein usually connects the inferior and superior vena cavas. While Marietess did not have a functioning inferior vena cava, she had two superior vena cavas, rather than one. Blood from the azygous vein drained into the right superior vena cava and then into the common atrial chamber of Marietess's heart. The additional, left superior vena cava drained blood from the left side of her head and her left arm and entered her heart at the coronary sinus. This is the site through which blood normally drains from the heart muscle after oxygenating the heart muscle itself. As a result of the presence of the left superior vena cava, this sinus was enlarged. Thus, blood from the left SVC joined the venous return from the heart muscle and emptied into the common atrial chamber. Marietess's patent ductus arteriosus remained open on its own.

Marietess had, essentially, only one functioning ventricle: the right ventricle. All the surgical plans developed for her were designed to optimize that ventricle's pumping capacity. In addition, she had muscular obstruction below her pulmonary valve. This compromised blood flow to her lungs. Both these factors necessitated a systemic to pulmonary artery shunt (a left-modified Blalock-Taussig shunt). This shunt joined the left subclavian artery to the left pulmonary artery, to provide more pulmonary blood flow. Some blood would be ejected out of the aorta and go to the body and organs, but some blood would flow back to the pulmonary artery via the shunt to be oxygenated in the lungs and then return to the heart.

Dr. Kim Duncan treated Marietess following her birth in 1991. His initial plan for treatment was to insert a Blalock-Taussig (B-T) shunt as a palliative measure and then carry out a definitive repair when Marietess was older and stronger. When Marietess was three months of age, Duncan performed the initial palliative repair as planned. Duncan revised the B-T shunt when Marietess was six months old, to allow more blood to flow to her lungs.

Marietess continued to be seen at the Variety Children's Heart Centre. When Dr. Niels Giddins examined her on December 13, 1993, she had no specific cardio-respiratory symptoms. Her chest was clear, her peripheral pulses were good and her liver was not enlarged. While she was cyanotic and had clubbing of her fingers and toes, she did not need any medications. Her mother was told that since Duncan had left Winnipeg, it might be necessary for Marietess to undergo surgery in Saskatoon. A follow-up appointment was scheduled for early 1994.

THE DECISION TO OPERATE

On May 2, 1994, Giddins presented Marietess's case at a CVT conference. In Odim's opinion, Marietess was at the point of outgrowing her shunt, which was creating a volume overload on her right ventricle. He suggested a bilateral, bi-directional, cavo-pulmonary shunt, with removal of the existing B-T shunt and an atrial septectomy. This surgery is a Fontan-type procedure, sometimes referred to as a bilateral Glenn procedure or a Kawashima operation.

In the procedure that Odim proposed, the right superior vena cava was to be surgically connected to the right branch of the pulmonary artery, instead of to the right atrium. The left superior vena cava was to be surgically connected to the left branch of the pulmonary artery, instead of entering the coronary sinus. It is called bilateral because it involves the superior vena cavas on both the left and right sides of the body. It is called bidirectional because the blood from the right superior vena cava flows to both the right and left lungs. It is called a cavopulmonary shunt because it was to connect the vena cavas with the pulmonary arteries.

All the oxygen-depleted blood that normally drained into the right atrium would, in this case, be draining through both of the superior vena cavas into the lungs. The right superior vena cava was attached to the right pulmonary artery and the left superior vena cava was attached to the left pulmonary artery. In addition, a septostomy was performed to remove the remnants of the septal wall between the right and left atria. The result was that blood flow from her body would continue to drain into the right superior vena cava, which would also drain the right upper body. The left side of her upper body would continue to drain into the left superior vena cava. Therefore most of the venous or blue blood, which would normally be directed through the right side of the heart, would flow through the pulmonary arteries to the lungs by gravity, without the benefit of any pumping action from the right ventricle.

According to Dr. Glenn Taylor, the success of the operation depended on two things. First, there had to be low resistance to blood flow in the pulmonary arteries. Second, there had to be maintenance of a satisfactory gradient of pressure between the central venous pressure and the pressure within the common atrial chamber, which was also receiving the venous drainage from the lungs. The central venous pressure was the driving force for perfusion of the lungs, in comparison to systemic arterial pressure being the driving force where there was a Blalock-Taussig shunt (Exhibit 336, page 8.1).

While the pressures in a heart are always important, in this repair the pressures are particularly important. This is because the patient's blood circulation depends on a single pump, the right ventricle, to send the blood through both the body and the lungs. If there is any backup of blood flow, because pressures downstream are elevated, the child's heart will quickly start to fail. A variety of factors, including medications, blood clots, and suturing, can work independently or jointly to raise or lower pressures in the veins, with dramatic and potentially fatal impact.

CONSENT

Giddins testified that, during the spring of 1994, he felt that the parents' understanding of their daughter's heart problem was continuing to grow as a result of regular discussions with him and Odim. He also said he could not recall any discussion with the family about having the procedure performed outside Manitoba.

On June 6, 1994, Odim met with Ben Capili, Sarah Tena and Sarah's mother, Teresida Tena. At the end of the meeting, the family gave verbal consent to surgery.

Odim was asked what he recalled telling Marietess's parents about risk.

> Again I separated out the risks, as I usually do, into the risks of cardiopulmonary bypass, and the risks of Fontan operations, issues of prolonged chest tube drainage from the lung, issues of perhaps it not working, and that circulation not being tolerable. But we felt with the data we had in terms of the ventricular function and the AV valve function that if the pulmonary vascular resistance was reasonable that there was every good chance that it should work and told her that given 100 children like her, anywhere from 7 to 10 would have a problem with the operation. (Evidence, pages 25,436–25,437)

Ben Capili, Sarah Tena and Teresida Tena all testified. Because Ben Capili had to absent himself from part of the June 6 meeting to take care of Marietess, he was not present for some of the conversation with Odim. All three testified that Odim gave them no information as to the slowdown in the program. They were not told that only low-risk procedures were being performed in Winnipeg during the summer of 1994.

Sarah Tena recalled that at this meeting, Odim drew a diagram of Marietess's heart. Marietess's condition, she concluded, was more complex than she had earlier understood. She testified that Odim told her that he wanted to do a Fontan procedure. This would result in Marietess being left with a three-chambered heart that was fully functional. She recalled that she had asked twice about the risk to her child from the procedure, and was told by Odim that Marietess had a 97 per cent chance of success. She was told, however, that Marietess might be in the three per cent risk category for morbidity or mortality.

In her testimony, Sarah's mother, Teresida Tena, also confirmed that Odim gave this risk percentage at the meeting. Teresida Tena suggested that the operation take place in Toronto, since a friend's son had undergone surgery there and had done well. She testified that Odim had assured them that they were capable of doing the procedure in Winnipeg. Sarah Tena accepted that as fact, particularly since Marietess had been so well treated previously by Duncan.

When the meeting ended, the family was told that an operation would be scheduled, although they were not given an indication as to when surgery might take place. Sarah Tena thought it would take place during the summer.

Giddins testified that the success rate for operations of this type was 90 per cent, placing it on the high end of the moderate risk scale. He noted that the decision to set a date for Marietess's surgery took place in August. At the time that the operation was scheduled, the Winnipeg team was only handling low and medium-risk cases, with the decision to move to high-risk cases not being made until September. In his testimony, Cornel stated that he thought the risk of complications for this procedure was about seven to eight per cent.

The family was informed of the date for surgery in a letter dated August 30. They were told that Marietess would undergo her operation on September 13, 1994. Sarah Tena testified that the family thought that this was very short notice, but they did not raise any objections.

PRE-OPERATIVE STATUS

On September 12, Sarah Tena took Marietess to the HSC. The admitting medical student described Marietess's condition as stable. She had been experiencing fatigue and shortness of breath when playing and her oxygen saturation had fallen. She was somewhat cyanotic, and her fingers were clubbed.

Sarah Tena met with Odim again that day. She testified that Odim once more explained the procedure, although this time she said he told her that the risk was 93 per cent, a figure consistent with Cornel's assessment. Sarah Tena said that since she had already signed the consent form, she felt she was committed to going ahead with the operation.

Dr. Jo Swartz conducted an anaesthetic assessment on September 12. Swartz identified a number of issues that she believed could create difficulties with the procedure. Marietess had a slow atrial rate, a sign that she might require pacing. Because she was cyanotic, there was an increased risk of blood clots. Swartz classed Marietess as ASA IV, a sign that her overall condition presented a constant threat to her life.

It should be noted that there was no evidence presented to this Inquest that suggested that any errors were made in the diagnosis, in planning the operation, or in carrying out pre-operative care.

THE OPERATION — SEPTEMBER 13

On the morning of Tuesday, September 13, Marietess underwent an operation in which:

- a bilateral and bi-directional caval pulmonary anastomosis was created (this term refers to the joining of the superior vena cavas to the pulmonary arteries);
- the opening in the septal wall between her two atria was enlarged;
- her Blalock-Taussig shunt was removed; and
- her patent ductus arteriosus was closed.

The surgical team is set out in the accompanying chart.

TABLE 8.1: Persons involved in the operation on Marietess Tena Capili, September 13, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	S. Sharpless
Anaesthetist	J. Swartz, R. Debrouwere (resident)
Scrub nurses	C. Weber, S. Scott
Circulating nurses	C. Youngson, B. Zulak
Perfusionists	D. Smith, C. McCudden

TABLE 8.2: Length of phases of the operation on Marietess Tena Capili, September 13, 1994

Phase of the operation	*Time taken*
Induction	2 hours 10 minutes
Bypass	4 hours 34 minutes
Aortic cross-clamp	22 minutes
Total surgical time	9 hours 1 minute
Total operating-room time	11 hours 56 minutes

There were four significant events during surgery. They were:

- Cannulation issues;
- Problems with distension of the heart;
- Coagulopathy and surgical bleeding; and
- Superior vena cava syndrome.

Cannulation issues

Before Marietess went on bypass, a problem with cannulation gave rise to bleeding and a fall in blood pressure. Youngson testified that it appeared to her that Odim was having difficulty cannulating the superior vena cava. In particular, she thought, he was not using an appropriately sized cannula. She said:

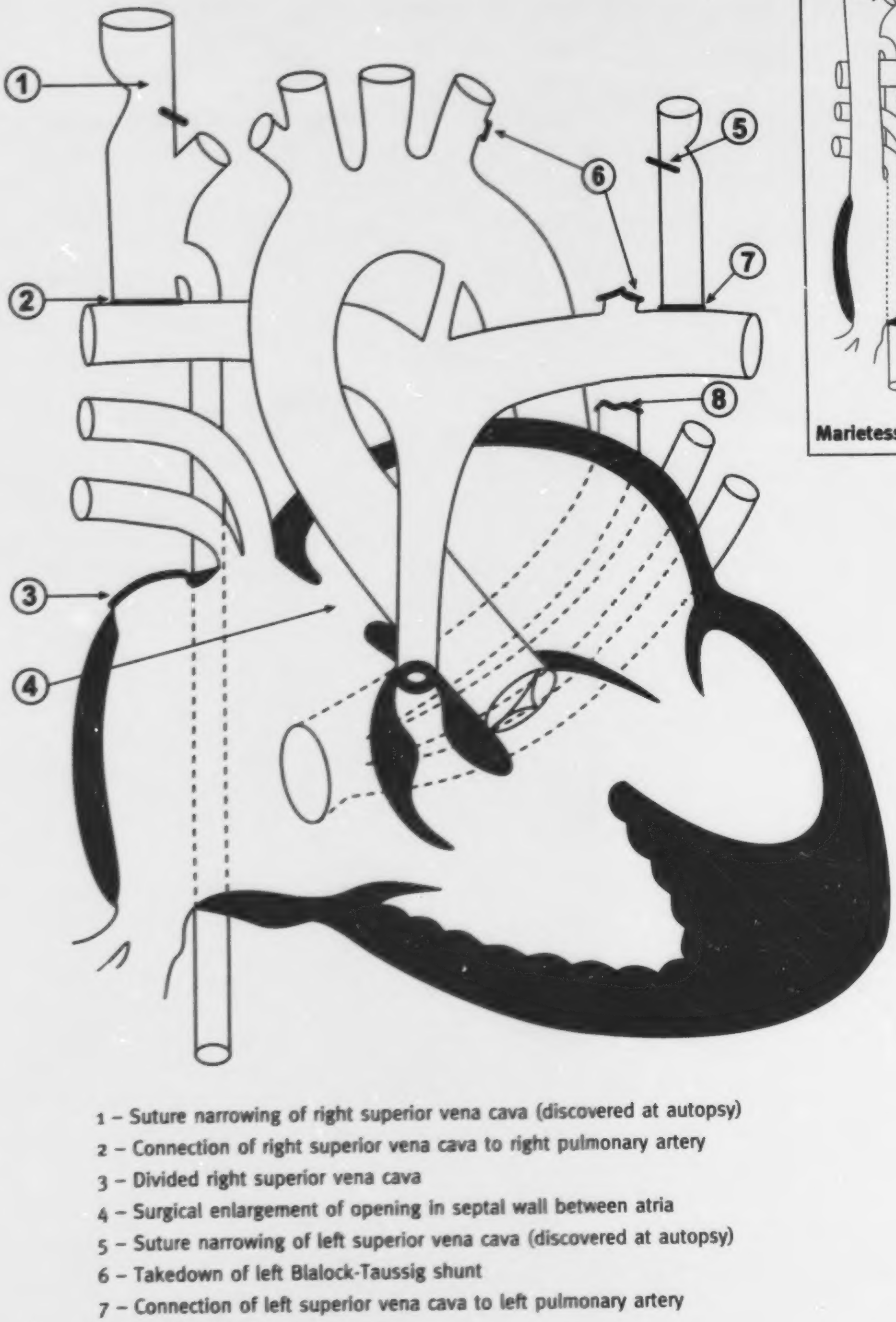
> No, to me it looked too big. I pointed it out to him at some point in time—I can remember looking over, I was circulating nurse, I was around at the top of the bed and looking over the top and watching him cannulate.
>
> I could see that this cannula wasn't going to go into this vessel. You know, I didn't say anything at first. Then as he struggled to get it in, I know I sort of quietly said, it's too big, it's too big. And I thought, well, maybe he would be the only one that would hear me say that. And he tried a couple of times, and I think he tore the vessel. So he stopped, and he had to suture the vessel. I think then he went to a smaller cannula and cannulated.
>
> I think at that point in time, I can't remember if this was the first, second or third cannula, venous cannula that went in. I think it was either the first or second, and Marietess was bleeding at that point in time and starting to—her blood pressure was starting to fall and things were starting to, you know, get a little more urgent. (Evidence, pages 8,581–8,582)

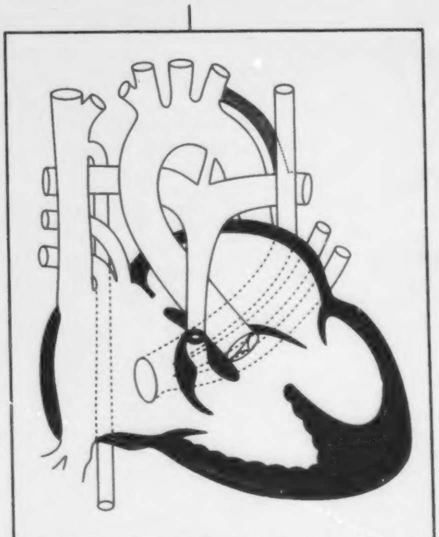
Once the cannulas were inserted and the lines connected, blood was supposed to flow to the bypass machine. However, the perfusionist reported that the flow from the child was low. Youngson testified that at this point the operative field was very disorganized. However, she was able to see that one of the cannulas was clamped, preventing a flow of blood away from the body. She told the surgeon and the line was unclamped. Swartz confirmed this event in her testimony. Marietess was transfused and treated for the fall in blood pressure. These events took place at approximately 1145 hours.

When Odim was questioned about this series of events, he suggested that the problem was that the anaesthetist had not prepared for what he termed 'volume overload' in time to prevent a drop in blood pressure. He gave the following account:

> I know that that dissection was difficult, because it was in the area of the chest of the previous shunt and there had been a couple of operations on that side. So dissecting out the shunt was quite difficult on the left side and the left superior vena cava was essentially quite near that area.
>
> When we had, that was sort of the last structure that was cannulated, the aorta was cannulated, the right atrium was cannulated, and the right SVC or superior vena cava was cannulated, and that was a large structure. When we cannulated the left SVC, it was a little difficult when we opened, and I had to make a couple of passes with the cannula. During those attempts was when the blood volume was infused.
>
> Now, typically what happens is if there is some coordination between surgeon and anaesthetist, the blood pressure is low prior to opening that vessel, you volume load beforehand so that when you do open the vessel to put the cannula in, your tank is not empty. And I think the volume loading occurred a little late here.
>
> *Q:* Okay. So let's back up on that. You indicated if there is coordination between the surgeon and the anaesthetist –
>
> *A:* That's right.
>
> *Q:*—then you might volume load beforehand, anticipating that problem?

Diagram 8.2 Marietess Tena Capili – post-operative heart





Marietess Tena Capili – pre-operative heart

1 – Suture narrowing of right superior vena cava (discovered at autopsy)
2 – Connection of right superior vena cava to right pulmonary artery
3 – Divided right superior vena cava
4 – Surgical enlargement of opening in septal wall between atria
5 – Suture narrowing of left superior vena cava (discovered at autopsy)
6 – Takedown of left Blalock-Taussig shunt
7 – Connection of left superior vena cava to left pulmonary artery
8 – Divided left superior vena cava

> *A:* Exactly, because when you cannulate and you compress structure and open structure, you know by definition that you are going to have some blood loss as you open the vein. If your blood pressure is low beforehand, what anaesthesiologists will do is actually start giving volume, knowing that the next step is going to be opening that cava. (Evidence, pages 25,457–25,458)

Odim said that three vessels had already been cannulated and that Swartz should have provided more volume beforehand, thus making the procedure smoother. He said that this would have prevented the drop in blood pressure and the need to treat Marietess with drugs. He also indicated that he could not recall the clamped line to which Youngson referred.

Problems with distension of the heart

At 1440 hours, Marietess's heart became distended (or filled with blood due to a lack of drainage of blood from the heart). Swartz testified that the problem occurred because the catheter that was inserted into the heart to drain (or vent) it of blood had been displaced. She testified:

> In this case, it appeared what happened was that the vent had come out and the heart had gradually swollen up or filled up. And if it fills up to the point where it is not being—where the arterial blood going in is not enough, is not of high enough pressure with the pressure within the heart, the heart becomes ischemic. (Evidence, page 16,092)

In this situation the heart was not short of blood—it was actually filling up with blood. However, that blood was not leaving the heart, and the pressure from this build-up was keeping the oxygen-rich blood from entering the heart muscle. Swartz testified that Odim replaced the catheter and she treated Marietess with neosynephrine. Surgery then proceeded.

Surgical bleeding and coagulopathy

At 1648 hours, the team began to wean Marietess from bypass. Her blood pressure was low and she had a metabolic acidosis, suggesting that her heart was not beating well enough to meet the metabolic needs of her body.

Marietess was bleeding from the sites where the vena cavas had been connected to the pulmonary arteries, and she also had a coagulopathy. In response, the team transfused over five times her blood volume into her. The coagulopathy was also treated with medication, and Odim addressed the surgical bleeding.

The superior vena cava syndrome

After Marietess's chest was closed, Swartz became concerned that, when she listened to the chest with a stethoscope, the left side of her chest did not sound as good as the right side. Swartz therefore requested that a chest X-ray be performed. While this was being done, Odim left the OR to speak with the parents. As the X-ray was being taken, Marietess's head became increasingly swollen and purple-coloured. Swartz thought that Marietess was developing what is known as superior vena cava (SVC) syndrome. This syndrome results from partial or complete obstruction of blood flow in the superior vena cava. Swartz and Odim provided different accounts of what transpired once Odim returned to the OR.

Swartz testified that when Odim returned, the pressures in Marietess's left external jugular vein were measured. According to Swartz, Odim was concerned that:

> the adrenaline was causing vasoconstriction and that we were infusing the adrenaline into the external jugular vein. He had put in a left atrial line, and we moved the adrenaline from the left external jugular to the left atrial line, and then we measured the pressure in her external jugular. (Evidence, page 16,127)

A pressure reading of 35 millimetres of mercury (mm Hg) was measured in Marietess's left external jugular vein (a vein that connects to the left superior vena cava that is returning blood to the lungs). This measurement was about twice what Swartz believed the value should have been. Swartz concluded that the increased pressure showed a blockage in blood flow from the brain. This blockage was causing the brain to swell and was also starving the lungs of blood.

Patients who undergo Fontan procedures are usually kept in a head-up position to assist blood flow from the head to the heart. However, because she had just had an X-ray, Marietess was lying on her back when Odim returned. Odim testified:

> And one of the, either technicians or nurses at the head of the table said, oh, by the way, we had been running epinephrine through that line that was transducing this pressure, but we have taken it out and we have put it in another line. And at that point I was concerned about a pharmacological, pharmacologically induced obstruction on this side related to epinephrine and its vasoconstriction or vaso tightening effects in the system. (Evidence, page 25,482)

In his testimony, Odim explained that he believed the signs of the SVC syndrome were being caused by a response to the epinephrine (or adrenalin). He also indicated that he thought other team members shared the same belief, since he believed they had switched the epinephrine to another site, once the swelling had become apparent.

Odim testified that it was not common to infuse a vasoconstrictor, such as epinephrine, into the pulmonary system, since pulmonary vessels are prone to constricting. He said that it was more appropriate to infuse vasodilators into such a system. Odim testified that he had no problem with Marietess being treated with epinephrine, but he did not want the drug infused into the left external jugular vein (which flowed to the lungs).

He testified that he suspected that the problem was caused by the epinephrine because pressures had been stable for the two hours that he took to close the chest. For all these reasons, he concluded that recent administration of epinephrine had led to a constriction and the SVC syndrome.

This differs from Swartz's account in that Odim indicated that the switch in the site of infusion of the adrenalin was made before he returned to the OR. It is a significant point because, while they were in the OR, Odim and Swartz had a serious disagreement about both the cause of the SVC syndrome and how it should be addressed.

While Odim suspected that the adrenalin had caused the pressure elevation, Swartz believed there was a physical obstruction. Odim claims that he reached his conclusion about the role that the drug played in bringing on the SVC syndrome, in part because team members told him that after the pressures increased they had switched the adrenalin site. However, according to Swartz, the adrenalin was moved from the left jugular line to the left atrial line at Odim's direction after he returned to the OR and after the SVC had been detected. There was also no indication, she said, that the other team members believed the problem was linked to the adrenalin.

At the time, Swartz suggested to Odim that either an echocardiogram or a 'line-a-gram' be performed to detect any blockage. In a line-a-gram, dye is injected into the bloodstream or into the line and an X-ray is taken. This X-ray provides an indication of where blood flows and where any blockages might lie. According to Swartz:

> I had seen this before, actually. It was a similar problem, and we had done a line-a-gram, we had identified an obstruction. The patient had an obstruction because of clot, actually, and the clot was removed and the pressures came back down. And since that was a simple problem, it seemed to me, maybe this was an equally simple problem. (Evidence, page 16,136)

Swartz believed that it would be preferable to identify the problem in the OR, where, if necessary, the source of the swelling could be addressed, rather than attempting to address it in the PICU.

Odim testified that he believed the problem was caused by the adrenalin and could be best treated with drugs in the PICU. He said he did not wish to carry out the types of tests that Swartz was recommending because he felt such tests would not have indicated the cause of the blockage, merely its location. Odim also testified that the dyes used in a line-a-gram could also lead to problems.

Swartz and Odim consulted with Giddins, who also felt that the problem was a narrowing or spasm in the vein caused by medication flowing through the left external jugular line. Giddins agreed with Odim that the best course of treatment would be to take Marietess to the PICU and begin hyperventilation and vasodilator therapy. Swartz testified that she was very unhappy with the decision to leave the OR. She also testified that Giddins told her that Marietess's appearance was not uncommon.

In his testimony Giddins could not recall a serious disagreement between Swartz and Odim and himself over whether or not Marietess should be taken out of the OR. Giddins was asked if consideration was given to stabilizing her in the operating room.

> No. In the opinion of all, at the end of the operation, there were set strategies that were felt to be best carried out in the intensive care unit and, in fact, would not be as ideally done in the operating room. (Evidence, pages 4,019–4,020)

Swartz, however, insisted that she made it very clear that, in her opinion, it was not the best strategy to move Marietess to the PICU.

POST-OPERATIVE COURSE

During transfer to the PICU, one of the lines that Odim had constructed fell apart and had to be repaired. Marietess's condition never significantly improved, once she was transferred to the PICU at 2020 hours. She was cyanotic, air entry to her lungs was poor and she had a severe respiratory and metabolic acidosis. Her head and neck remained swollen. While the pressure in her left external jugular decreased for a period of time, it remained high. As a result, the flow of blood to her lungs and heart remained poor. This lack of blood flow played a major role in the heart failure that led to Marietess's death.

Dr. Ellsabete Doyle, who admitted Marietess to the PICU, indicated in her notes that Marietess was at risk of impaired blood flow to her brain and her lungs and also at risk for heart rhythm problems. In his testimony, however, Giddins said that Marietess's condition was normal for a child following this procedure.

Odim wanted to have Marietess treated with vasodilators and nitroglycerin as soon as possible in the PICU, in an attempt to dilate her vein and lower her pressures. Swartz had ordered nitroglycerin while the team was in the OR; however, treatment with this drug was not started until 2047 hours, almost half an hour after her arrival in the ICU. No satisfactory explanation has been offered for this delay.

The pressures in the left external jugular vein dropped to the mid-twenties once Marietess was in the PICU. Giddins concluded that: "It appeared that the measures that we had planned on starting in the operating room during transfer were working." (Evidence, page 4,004) Odim felt that during the first few hours in the PICU, Marietess's condition was "moving slowly in what appeared to be the right direction." (Evidence, page 25,548)

However, Marietess's perfusion remained poor, and while the pressure in the left external jugular did drop, it never approached an acceptable reading. After approximately three hours in the PICU, those readings began to increase once more. Between 2100 and 2130 hours, the pressure in her left jugular vein ranged between 29 and 33 millimetres of mercury.

A chest X-ray taken in the PICU showed how seriously Marietess's heart was failing: both her lungs were collapsing and the X-ray report described them as airless. The team undertook a variety of steps to try to improve her condition, including using hand ventilation. However, her oxygen saturation continued to fall, while the amount of carbon dioxide in her blood increased. Marietess was treated with vasodilators, at their maximum doses.

Odim and Giddins felt that, given Marietess's fragile condition, they could not perform a line-a-gram. As time passed, the pressures on the right side of her body began to rise.

Marietess also experienced an abnormally fast heart rhythm, called junctional ectopic tachycardia (or JET), which reduced her cardiac output. Attempts were made to slow the heart rate by cooling Marietess and treating her with digoxin. At 0110 hours, Marietess had her first cardiac arrest. The team in the PICU began cardiac compressions, which were continued intermittently until 0313 hours, when Marietess died.

THE FAMILY ON THE DAY OF SURGERY

Ben Capili and Sarah and Teresida Tena were all at the hospital on the morning of the operation. According to Ben Capili, Lois Hawkins came out to speak with the family about the progress that was being made. Sarah Tena testified that Hawkins came to see them about every four hours. When they asked why the operation was taking so long, Sarah Tena recalled being told that the procedure had started late and there had been problems with unexpected bleeding. Teresida Tena also said that Giddins also brought the family updates on surgery during the course of the day. She testified that at 1730 hours Giddins informed them that there had been bleeding, but that it was under control.

Ben Capili testified that Odim came out of the OR to tell them that the operation had gone well and her blood flow was improving. As a result, they were told, Marietess would not have such severe cyanosis and would be looking less blue when they next saw her. Teresida Tena and Ben Capili also testified that, at the end of the operation, Hawkins told them that Marietess would no longer be blue when they saw her next.

When the family finally saw Marietess in the PICU at approximately 2100 hours, they were shocked. Her head was not only very blue, it was swollen. The nurse in the PICU told them that Marietess was in serious condition. No one spoke to them about her prospects. However, while they were at her bedside, an alarm sounded, and the nurse told them that they had to leave. The family left the PICU and waited for news. Sarah Tena was allowed to see Marietess after a while. Although Marietess was still heavily sedated, her mother spoke to her.

Giddins told them that Marietess was in critical condition. According to the family, however, there was no suggestion that Marietess would not survive the night, and Ben Capili and Teresida Tena went home. Sarah Tena stayed behind. When a nurse told her that Marietess's condition was getting worse, she phoned Ben Capili and Teresida Tena at approximately 0200 hours and told them to come back to the hospital. The family sat in the waiting room. Giddins informed them that Marietess's condition was poor and that it would take a miracle for her to survive. He came out one final time to tell them that she had died. A short while later, Odim came out to speak with the family.

Sarah Tena testified that, during the course of the whole evening, from the time that the operation was completed and Marietess was taken to the PICU, they had not been able to see her, except for a few minutes. The family, with some justification, believed that the seriousness of Marietess's situation was not properly communicated to them throughout the operation or the post-operative period.

OPERATIVE REPORTS

Odim prepared two summaries of this operation. One was his operative report; the second was a letter that he wrote on September 14 to Grewar. In both he indicated that there were no technical difficulties during surgery. In the letter to Grewar, he wrote that Marietess's condition on return to the PICU was "satisfactory but critical." He also wrote:

> Of concern in the Intensive Care Unit was an increase in venous pressure on the left side with accompanying signs of superior vena cava syndrome.
>
> The left-sided pressures which had been corresponding to the right-sided central venous pressures shortly after operation peaked at 35 cm of water. With infusion of Nitroglycerin through the system on the left side these pressures started to drop and her clinical condition improved. (Exhibit 5, page CAP 52)

He stated that after a period in which Marietess's condition moved in what he thought to be the right direction, Marietess experienced high central venous pressures, poor ventilation, and a collapse of her lungs. He wrote that:

> We considered taking her back to the operating room to take-down this Fontan type connection and reconstruct a systemic to pulmonary artery shunt but felt that she would not survive another bypass run. (Exhibit 5, page CAP 52)

Odim indicated that if any new information emerged from the post-mortem, he would forward it to Grewar.

In his operative report, Odim stated:

> In the head up position there was some clinical improvement of the upper head edema and we returned to the Intensive Care Unit where Nitroglycerin was selectively infused into the left venous side with evidence of resolving high venous pressure. (Exhibit 5, page CAP 87)

In his testimony, Cornel stated that the bleeding that preceded coming off bypass was an important problem that took considerable action to correct. In his report, he wrote:

> The surgeon did not report any technical difficulties with venous cannulation but judging from the anaesthetic record there were significant difficulties and cannulation problems with these cases represent [sic] serious technical complications. (Exhibit 353, page 52)

In his report for this Inquest, Dr. Robert Hudson noted that in neither his operative report nor his letter to Grewar did Odim discuss the incident of hypotension (low blood pressure) that occurred at the time of initial cannulation in the OR. He noted that "severe hypotension just prior to CPB can aggravate the adverse effects of CPB on the heart." (Exhibit 307, page 8.11) Hudson also stated that he could find no evidence in the record to suggest that the nitroglycerin infusion resolved the high venous pressure as Odim suggested. Throughout her stay in the PICU, Marietess's pressures remained high. Soder was asked if he believed that the pressures were ever resolved. He pointed out that, throughout her stay in the PICU, Marietess's venous pressures were above 20, often by significant amounts.

> We get very concerned with pressures over 20, we are moderately concerned between 15 and 20, 20 is kind of the upper limit of what is acceptable. And even if you have pressures around 20 after one of these, you would like to see them over the next 24 hours come down into the mid teens.
>
> So, in my opinion, the fact that the pressures were in that range and the patient was doing very, very poorly in terms of being acidotic, there clearly was much evidence that this was not going the way it should. (Evidence, page 44,156)

The evidence would therefore seem to suggest that both the operative report and the letter to Grewar were incomplete and misleading. Contrary to the indication in those documents, there were serious technical difficulties during this operation. Those difficulties lengthened the operation and may have put stress on Marietess's heart. Odim should have mentioned the hypotension and the bleeding that occurred during cannulation. The letter to Grewar also left the impression that the SVC syndrome was identified in the PICU rather than in the OR. Neither the letter nor the operative report mentioned Swartz's proposal to have tests done in the OR to determine the cause of the SVC syndrome.

In the letter to Grewar, there is mention of a discussion in the PICU about whether or not Marietess was strong enough to be returned to the OR. This was a discussion that Swartz testified she did not take part in or was even aware of. If Odim thought it appropriate to mention this later discussion (whose conclusion appears to have been foregone), one has to wonder why he failed to mention the earlier discussion in the OR with Swartz.

There was nothing satisfactory about Marietess's condition when she arrived in the PICU. Her perfusion was poor and never significantly improved. The evidence suggests that the treatment that Odim and Giddins settled upon did not address her underlying problems. Those problems were only identified at her autopsy.

POST-MORTEM FINDINGS

Dr. Susan Phillips conducted the autopsy on September 15, 1994, with Swartz present as an observer. The autopsy report was completed on November 29, 1994. The autopsy made two important discoveries. The first discovery was that both of Marietess's superior vena cavas had been narrowed by the purse-string sutures that Odim employed when cannulating. The narrowing was more severe at the superior vena cava on the left (into which the left jugular vein drained) than at the superior vena cava on the right.

The second discovery was of a fresh clot or hematoma surrounding her left pulmonary artery and the hilum of the left lung. The hilum is the area where airways, blood and lymphatic vessels and nerves enter or leave the lungs. Phillips wrote that these two factors were the likely cause of the poor blood flow to Marietess's lungs, particularly on the left side. The narrowing of the superior vena cavas would have reduced blood flow to the heart. In the same way, the hematoma would have pressed on the pulmonary artery and also reduced blood flow to the heart.

Taylor believed that the clot likely arose from the removal of the Blalock-Taussig shunt. Soder testified that he believed it was likely that the clot did not form until the post-operative period, since Marietess was treated with anti-clotting agents during the operation. He also said that it was likely that it did not cause the high pressures noted immediately after surgery, since blood could still flow into the right lung if entry to the left lung were blocked by the clot.

FINDINGS

At the outset of this section, the following issues were identified:

- Should the operation have been performed in Winnipeg or should Marietess have been referred out of province?
- Were Marietess's parents provided with sufficient information to allow them to give informed consent to the procedure?
- What caused the superior vena cava syndrome?
- Should the surgical team have kept Marietess in the OR until the cause of the superior vena cava syndrome from which she was suffering was identified?
- What was the cause of death and was it preventable?

Should the operation have been performed in Winnipeg or should Marietess have been referred out of province?

- Findings

This was a very complex operation, requiring, as Dr. Walter Duncan indicated, excellence in performance. Given the problems that the team had experienced up to that time, it is likely that this case was beyond the capabilities of the team in September 1994.

Despite the conclusion of the Wiseman Committee's interim report, the team clearly continued to face a number of difficulties. In this case, there were not only problems in the operating room with cannulation and a very lengthy bypass, but also conflicts over treatment that, at the very least, showed serious communication problems. Therefore, the evidence tends to suggest that Marietess should have been referred out of province.

Were Marietess's parents provided with sufficient information to allow them to give informed consent to the procedure?

- Finding

Marietess Tena Capili's parents were not informed of Odim's experience, either with this set of defects or in general. Nor were they informed of the program's recent history. This evidence tends to suggest that Marietess's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

What caused the superior vena cava syndrome?

From the evidence, it appears that the prime cause of the SVC syndrome was the suture narrowing at the cannulation sites. In their joint report, Duncan and Cornel wrote:

> Unfortunately **the significant obstruction at the cannulation site meant that the blood could not get from the venous pool past the surgical anastomosis to the lungs.** (Underlining and bolded in the original.) Dr. Cornel and myself felt that the specimen explains the demise of this patient by demonstrating the important cannulation stenosis. (Exhibit 354, page 11)

None of the consulting witnesses who appeared before this Inquest believed that the SVC syndrome was pharmacological or drug-induced.

Cornel was asked about Odim's concern that there was pharmacological basis for the problem.

> If a large dose of a vasoconstrictor substance is run directly into the lungs, yes, it can cause pulmonary, an episode of pulmonary hypertension. Whether it could be to this extent, I don't know. But it doesn't really change what I said. If the blood is not flowing through the lungs because of pulmonary hypertension, it's not flowing through the lungs. And I would then take the operation down. (Evidence, page 44,865)

Soder was also asked if adrenalin could have had the sort of effects that Marietess experienced. He replied:

> It could transiently produce a profound increase in pulmonary artery pressure, but the pharmacological affects of adrenaline would last for a very short time. And after discontinuation of the adrenaline, within a few minutes, one would expect the pulmonary artery pressures to return back down promptly. It is a very short acting drug.
>
> *The Court:* Back down to what?
>
> *The Witness:* To the normal levels. If the theory is that the infusion of adrenaline caused pulmonary hypertension to a given level, then withdrawing the adrenaline should return the blood pressure back down to controlled levels within two to three minutes after discontinuation. (Evidence, pages 44,148–44,149)

Hudson was asked if it was wise to see if a pharmacological remedy would work. He replied that he would want to undertake a diagnostic manoeuvre, such as angiography (or the intravenous injection of dye and the taking of an X-ray to study the blood vessels). He was also asked how long it would take to see results from using a vasodilator to decrease the central venous pressure.

> If you were to give a vasodilator at an appropriate dose, and I have no idea what the doses were, those drugs act rapidly. So, you would see an effect in minutes. (Evidence, page 40,010)

In discussing Marietess's post-operative care, Soder stressed that the treatment she received in the PICU was doomed to fail, since it was based on a faulty diagnosis.

This was one of the cases that Soder identified as leading to his conclusion that:

> **the skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations.** (Boldface in the original.) (Exhibit 345, page 8)

■ Finding

The evidence suggests that the SVC problem was surgical in nature, that the surgeon's decision to transfer Marietess out of the OR was questionable and that the treatment he supervised in the PICU could not address her underlying problems. The evidence also suggests that Swartz believed this to be the case but was unable to influence Odim or Giddins on this point.

Should the surgical team have kept Marietess in the OR until the cause of the superior vena cava syndrome from which she was suffering was identified?

Several of the consulting witnesses who appeared before this Inquest addressed this issue. They were generally of the view that it was inappropriate to move Marietess from the OR without first conducting further examinations as to the cause of the SVC syndrome.

Cornel testified that the increase in the left external jugular pressure meant that there was either an obstruction in the veins or an obstruction of the blood flowing into or out of the lungs. He said that either the problem with the veins had to be addressed or the repair had to be taken down and the previous shunt re-established. In either case, Cornel testified, the problem had to be addressed in the OR. He said that it would have been possible to locate the problem in the veins by attaching a needle to the end of a line connected to a pressure monitor and inserting the needle into various sites in the veins. By doing this, Odim would have been able to get pressure readings quickly.

In his report, Dr. Walter Duncan wrote that if tests had shown "compression of the anastomoses or intrinsic narrowing, urgent revision and/or decompression might have been attempted—although this would have been a high-risk undertaking." (Exhibit 20, document 363, page 10) In his testimony, he stated that tests in the OR could have identified the suture narrowing that was discovered at autopsy.

Soder testified that the team should have first looked for blockages before leaving the OR. He stated that he would have examined the sites of anastomosis where the vena cavas and pulmonary arteries had been joined. If that failed to identify the problem, he said he would then have recommended that the team take pressure readings through a needle puncture, as described by Cornel. After that, he would have attempted to reduce the pulmonary pressures, since it would appear that Marietess had some form of pulmonary hypertension.

> But it is relatively, given that you can do the needle pressures, which you generally can, it makes it possible to sort this one out right in the operating room before going any further. I was surprised that this wasn't, I saw no evidence this was done.
>
> I was surprised to find that they leaped to the conclusion that this must be pulmonary hypertension, treated [her] as such, and took [her] to the intensive care unit. (Evidence, pages 44,140–44,141)

Soder testified that the approach that Odim and Giddins employed was for the treatment of pulmonary hypertension that was caused by a medical problem and not by a mechanical or surgical problem. When asked if he would have left the operating room with the child in this condition, Soder testified:

> I would have locked the door. There is no way I would have accepted a medical explanation for what I was seeing. (Evidence, pages 44,143–44,144)

In conclusion, Soder said that Marietess should not have been taken from the OR until a surgical exploration had been conducted to identify the cause of the SVC syndrome.

Hudson in his testimony suggested hunting for variations in pressures with a needle, as Cornel and Soder had both recommended.

- **Finding**

Based on the information in the autopsy and the opinions of the consulting witnesses, it is apparent that Marietess should not have been transferred from the OR until further tests had been carried out to determine the cause of the SVC syndrome. The evidence presented to this Inquest indicates that if the proper tests had been conducted in the OR, the surgeon might very well have discovered the suture narrowing of the blood vessels. Once discovered, the narrowing could have been addressed, allowing adequate blood flow. While there would be risks to undertaking such a repair, Marietess's life depended on the cause of the SVC problems being addressed immediately.

What was the cause of death and was it preventable?

- **Finding**

Marietess's death was due to failure of the primary repair. While there were no problems with the connection of the vena cavas to the pulmonary arteries, the surgeon inadvertently tightened the purse string sutures to the point where they narrowed the superior vena cavas. This led to the SVC syndrome, which was ultimately fatal. This conclusion is supported by a number of witnesses. Cornel and Duncan wrote:

> While the diagnosis and therapeutic plans were appropriate, the surgical outcome is explainable on an anatomical basis – namely the severe stenosis at the two venous cannulation sites. (Exhibit 354, page 11)

The evidence therefore suggests that Marietess's death was preventable.

THE APPOINTMENT OF DR. ANDREW HAMILTON

In September 1994, Dr. Andrew Hamilton took up a position as an adult cardiac surgeon at the HSC. Because Hamilton's residency training had included pediatric cardiac surgery, Dr. Robert Blanchard and Dr. Helmut Unruh spoke to him before he started at the HSC about his undertaking pediatric cardiac surgery, in addition to his adult cardiac surgery duties. As a result, his contract stipulated that he was to spend 15 per cent of his time performing pediatric cardiac surgery. Blanchard testified that it was initially intended that Hamilton would provide relief for Odim, rather than act as his assistant.

Hamilton took up his position in mid-September. Before that time, despite the implications that such a decision had for Odim, neither Unruh nor Blanchard spoke with him about their intent to have Hamilton look after pediatric cardiac surgery patients.

Despite Unruh's and Blanchard's intentions, Hamilton worked almost exclusively as Odim's assistant. He never did provide any significant relief for Odim, who continued to perform all the pediatric cardiac surgery at the HSC. The nurses and the anaesthetists testified that Hamilton's presence contributed to the smoothness of the procedures that he assisted in. They said that he communicated well and his confidence and competence greatly improved the atmosphere in the Operating Room.

According to Hamilton's evidence, at one point during the fall of 1994 (there is uncertainty about the exact date), Blanchard and Unruh decided that Hamilton would assist Odim at cases where there was a predicted mortality of 10 per cent or higher. The evidence is also unclear as to whether or not this information was communicated to Odim. It would appear that this decision was likely made sometime following the death of Erica Bichel, on October 4.

DR. BRIAN POSTL IS APPOINTED HEAD OF PEDIATRICS

On September 15, Dr. Brian Postl became head of pediatrics and child health at the HSC. Postl testified that he had been made aware of problems with the Pediatric Cardiac Surgery Program in late August or early September. Dr. Jack Bowman, who had been acting as Agnes Bishop's interim replacement over the summer months, had given Postl a short briefing on developments within the program. Bowman indicated that there had been problems, which were being addressed by a committee. A note from Bishop had given Postl similar information.

Postl said that, following his appointment, he began meeting with all the section heads who reported to him, as well as with the various pediatric health organizations in the city. He did not appreciate the magnitude of the problems that the PCS program faced for several weeks.

SEPTEMBER 20—THE CASE OF ML

ML was an 11-month-old child who underwent an open-heart procedure on September 20, 1994. She had originally been scheduled for surgery on May 19, 1994, but her operation was deferred because of the hiatus in the program.

This procedure included:

- creation of a bilateral, bi-directional cavopulmonary anastomosis
- ligation and division of a right modified Blalock-Taussig shunt
- ligation and division of a rudimentary main pulmonary artery
- ligation and division of the patent ductus arteriosus.

Youngson and McGilton acted as scrub nurses for this operation. McNeill was the anaesthetist, while Hinam provided anaesthetic nursing services.

In her testimony, Youngson said that ML arrested during the attempt to take her off bypass. At this point the aortic cannula came out. Youngson testified:

> Now, when we secure a cannula, when we cannulate initially, the aortic cannula is secured with a heavy piece of silk. It's what we call a super stitch. It's just a real heavy piece of silk that is tied around the cannula and sutured into the patient. So it holds that cannula in place so it doesn't come out.
>
> In all this excitement, I don't think that super stitch was put in. So the cannula came out. (Evidence, page 8,600)

According to Youngson's testimony, there was a danger that air would enter the cannula if it was being re-inserted quickly, as it was in this situation, and time was not taken to clear any air from the tip of the cannula. Youngson testified that she felt it necessary to remind Odim to de-air the cannula.

ML was put on bypass for a second time. At that point, the team did not know why she was arresting. After approximately half an hour, there was a second attempt to wean her off bypass. Once more her heart began to arrest.

According to Youngson's testimony, Odim seemed to think the arrest was being caused by a reaction to protamine or to blood products. Youngson testified that Hamilton disagreed, saying that it was something the surgeons were doing in the operative field that was causing the problem. McNeill, McGilton and Hinam corroborated Youngson's account of the difference of opinion between Odim and Hamilton over the cause of the arrest. McGilton testified that Hamilton stated that the arrests were linked to the surgeon's touching a certain part of ML's heart with the forceps. Eventually ML was weaned from bypass.

Youngson observed that ML had experienced considerable bleeding throughout the operation. She felt the child should not have left the OR until the bleeding was controlled. Despite these concerns, ML was taken to the PICU. Hamilton could not recall this case, and Odim was not asked about it.

ML was sent to the PICU without her sternum being closed. She had a lengthy stay in the PICU, and the first night was particularly difficult. Dr. Murray Kesselman attended ML in the PICU. Her significant bleeding problems continued from the time of her arrival until the next morning, requiring constant attention and blood transfusion. In addition, she had a difficult time with hypotension (low blood pressure) related to her ongoing bleeding. Kesselman called Odim back to the unit several times during the evening, to look for the cause of the bleeding. For the first few times, Odim said, the bleeding was the result of a coagulopathy. Kesselman was not certain that that was the case; however, he testified, "The surgeon comes and looks around and says there is nothing for me to suture. So, that's what you go with. That's what you have to deal with and cope with." (Evidence, page 34,067)

ML's condition did not respond to treatment for coagulopathy and, in Kesselman's opinion, she was in serious danger from ongoing blood loss. She suffered a cardiac arrest late that night, but was resuscitated. At about 0700 hours the next morning, Odim sutured blood vessels in ML's chest and the rapid blood loss stopped. This clearly suggests the blood loss was surgical and not a coagulopathy, as Odim had earlier insisted. From then on, the PICU team was able to stabilize her. She was discharged on October 16.

WISEMAN'S MEMORANDUM TO THE DEPARTMENT HEADS

On September 22, 1994, Dr. Nathan Wiseman sent a memorandum to Blanchard, Craig and Postl, announcing that the committee he chaired had recommended that the Pediatric Cardiac Surgery Program continue at a full level of activity. The committee was still going to meet regularly, and updates would be provided to the three heads.

ODIM'S LETTER OF SEPTEMBER 26

At the same time that the Pediatric Cardiac Surgery Program was returning to full operation, Odim wrote a letter to Blanchard outlining his assessment of the program. The contents and tone of this letter of September 26 suggest that Wiseman may have been too optimistic in his assessment of the work his committee had done to re-establish a measure of trust and confidence amongst team members.

Odim wrote that, when he had come to Winnipeg six months earlier as a young surgeon involved in restarting a complex and depleted program, he realized that the experience would not be easy. The letter went on to exhibit a high degree of frustration and even anger over the events of mid-May.

> Within two and one-half months of my welcome here, and unbeknownst to me, there was a concerted effort by the department of anesthesia at the Children's Hospital to derail the efforts of a building, albeit fledgling, pediatric cardiac surgery program. In effect, this was accomplished by a "walk-out" and an alleged circulated memo to department heads and leaders within the Health Sciences Centre. I was not sent a copy of this memo and hence have neither read this manifesto nor did I receive the common professional courtesy of a priori discussion of their concerns. Naturally, these events have led me to question not only the commitment of these individuals to pediatric cardiac surgery, but their motives and more importantly, their character or lack thereof. In addition, I must confess that the basic trust that develops between surgeon and anesthetist as they care for a child in the operating theatre has certainly eroded [sic] by this conduct. One only hopes that this state of affairs is remediable and not irrevocable. (Exhibit 19, Document 255)

Odim testified that he was not imputing a specific motive to the anaesthetists, but was wondering aloud why they would have refused to provide anaesthetic care without first consulting him. He agreed that a lack of trust could have an effect on the course of an operation. In his testimony, Odim said that in late September he continued to trust the anaesthetists, adding:

> I don't think there was an issue of trust. At the time, my sense was that it was just a personality situation, some individuals seemed to hang tenaciously to their own concepts and practice, and I attributed some of that difficulty to personality, not trust or lack of trust. (Evidence, page 25,599)

When the portion of his letter that stated that the basic trust between surgeon and anaesthetist had been eroded was read back to him, Odim testified:

> Let's take a step back. The conduct is referring to the fact that they would withdraw services without the professional courtesy of discussing issues with the surgeon.
>
> Now, if this is their typical conduct, then how do I know when I go into the battle field that issues won't be discussed with me? And that's the intent, or that's the meaning of that statement. It has nothing to do with the fact that I didn't trust them. My concern was that if they could take a step like that, without discussing things with me, then I have to be concerned that this could happen in future, in the operating room, where there is silence and no communication. And that's the background to that statement. So the conduct I'm referring to is the manner in which things had happened. (Evidence, page 25,600–25,601)

Odim wrote that during the suspension of the program, 10 children had been sent out of province, with a 30 per cent mortality rate. In actuality, 14 cases had been transferred out of Manitoba during the hiatus. He complained that during this period, the anaesthetists dictated who could undergo cardiac operations in Winnipeg. While the program was now going to be working at full service, he said, there were a number of obstacles to its long-term success. To Odim, these obstacles related to anaesthetic services.

> When I arrived here in Winnipeg there was no leadership within the division or group for pediatric cardiac anesthesia. There are four part-time individuals of varying expertise and experience who participate in cardiac anesthesia at the Children's Hospital. It is difficult to figure out, on a case-to-case basis, which of the individuals is scheduled, particularly given the varying level of expertise and experience and the complexities of the cases. Furthermore, because of the limited caseload, no one of this group gets an opportunity to develop any considerable experience in order to maintain their skills in a rapidly changing field. In fact, skills in intraoperative transesophageal echocardiography, a standard throughout North America is lacking. While I am very sympathetic to their anxiety and comfort level, particularly since these individuals are all part-time who for the most part are involved in minor surgical, office based, day surgical, low anesthetic risk procedures at the Children's Hospital. Given the part-time nature of their commitment to pediatric cardiac surgery, it is quite understandable why such a group find four and sometimes five anesthetists necessary to cover 50–60 open heart procedures over a twelve month period. Unfortunately, this sharing of commitment and responsibility, dilution of experience, does not make for better patient care. When the pediatric cardiac surgery team evolved and it became readily apparent that there was no leadership in pediatric cardiac anesthesia, a spokesperson, who in my opinion has the least experience and expertise in pediatric cardiac anesthesia, was elected by vote. This is simply not a satisfactory solution. In addition, attempts to find out what the requirements are for maintaining skills in pediatric cardiac anesthesia at the Children's Hospital have been in vain. When rebuilding a pediatric cardiac surgical service commitment from all players is mandatory. Moratoriums simply skirt around the fundamental issues while rust and a loss of skills accrue from inactivity. (Exhibit 19, Document 255)

Odim then stated it was necessary to make more use of the expertise of the adult anaesthetic staff. He said there should be only two anaesthetists providing services on pediatric cardiac cases. He also believed that it might be necessary to recruit at least one of these two persons. Another solution would be to place cardiovascular anaesthesia under a single head. Odim also called for the consolidation of post-operative care.

In closing the letter, Odim stated that he would welcome an external review of the entire Pediatric Cardiac Surgery Program.

> To date, our internal review process has focused primarily on surgical issues. I think an expansion of this process to include other aspects, in particular the competence of pediatric cardiac anesthesia and the requirements for maintenance of skills in these areas. I think these issues are critical if the Children's Hospital is to discard its present masquerade as a tertiary care Children's Hospital for the province and central Canada. (Exhibit 19, Document 255)

Odim testified that he was not questioning the competence of the anaesthetists; instead, he was requesting an examination that would ask if people could maintain their competence while doing a limited number of cases.

Odim provided Blanchard with both a mission statement and a summary of his proposals. The latter included the development of a single cardiovascular anaesthesia service and the move to have two anaesthetists provide care for pediatric cardiac surgery, consolidation of the two ICUs and the appointment of a nurse clinician. In addition, Odim sought to expand service into the United States and establish relations with a pediatric cardiac centre in the Third World.

Odim also wished to perform pediatric heart transplants. Blanchard said he thought that the latter point in particular was unrealistic in Winnipeg.

Blanchard testified that he was surprised at the strength of feeling in the letter. He said that he had spoken to Odim on occasion during the summer and had been left with the impression that progress was being made on the issues in pediatric cardiac surgery. Blanchard was asked:

> Reading this letter, did it seem to be that perhaps that dissension, instead of being remedied by the Wiseman Committee, was ongoing and festering?
>
> ***Blanchard:*** That's all I could infer from this. (Evidence, page 36,597)

Blanchard was then asked:

> I guess what I was ultimately coming to is, after you read this letter and after you spoke to him, did you give consideration to either having—taking some steps, either an external review, slowing down the program, or doing something to get at these issues. Because if the letter is an accurate reflection of what Dr. Odim thought, it would suggest that the Wiseman Committee had not succeeded in a lot of these, in the issues in terms of inter-personal conflict. Would you agree with that statement?
>
> ***Blanchard:*** That was my assumption. So when I spoke with him I told him, you know, that he has suggested an external review. I said that an external review is a very serious matter, and I said, you know, if there is an external review, you will come under very, you know, strict scrutiny, as well as anaesthesia or whatever other things you might be concerned about. So you need to realize that too. But I said, do you really think that the problems are of that nature?
>
> And he said—well, I don't remember exactly what he said, but he was willing to go ahead with an external review, but at the same time he felt that the program was functioning okay. So I said, well, I will run this through the department heads, and we will talk about an external review.

> ***Question:*** So based on that assurance, and I guess whatever other information you had about the program, you allowed the program to continue and then started discussions about an external review, correct?
>
> ***Blanchard:*** Yes. (Evidence, pages 36,600–36,601)

Odim testified that several weeks after receiving the letter, Blanchard spoke to him a second time about an external review. He testified that Blanchard recommended waiting until Dr. William Lindsay arrived. Lindsay was coming to Winnipeg as the new head of cardiovascular and thoracic surgery and cardiology for both the HSC and St. Boniface General Hospital. Once he arrived, it was hoped that Lindsay might conduct a review of the program.

Odim's letter must be considered from a number of perspectives. First of all, it raises a number of quite legitimate matters. It was quite legitimate for Odim to question whether or not the program would be better served if there were only two, as opposed to four, anaesthetists. It was also quite legitimate to propose a different approach to post-operative care. Representatives from the Department of Anaesthesia did not agree with Odim's view on how many anaesthetists should provide care in the program. This was a matter of legitimate debate, just as the post-operative care issue was one on which there could be legitimate and differing points of view.

However, there is a great deal about this letter that is disturbing. Throughout the entire Wiseman Committee review, the evidence indicates that Odim acted in a restrained manner and raised only a limited number of issues. A number of witnesses indicated that he did not give any sign of having been personally wounded by what was undoubtedly a very distressing event, namely the May 17 memorandum and withdrawal of services.

Yet it is clear from this letter that the anaesthetists' withdrawal had touched him deeply. That is understandable. But many of the views expressed in this letter are little more than petulant. While Odim was not sent a copy of the May 17 memorandum, he was present at a meeting where it was discussed on the morning of May 17. He had every opportunity to read it and respond to it at that time. He seems to have stubbornly refused to do so, however.

Odim's comments on the anaesthetists' character and motives raises a more serious issue. It is not surprising that he harboured strong feelings towards the anaesthetists, but it is clear that these feelings went beyond personal dislike. In this letter he was indicating that, as a surgeon, he had lost much of his trust in them as anaesthetists. There is no indication that he raised this issue during the previous three months when the program was restricted to low-risk cases. If he had done so, then it is likely that it would have sparked a heated but needed discussion at the Wiseman Committee.

It is difficult to believe that the committee could have concluded that the program was ready to go back to full service if Odim had tabled such a letter or given voice to the sentiments in the letter at a committee meeting.

It is clear that Blanchard also found this letter disturbing. When Blanchard distributed the letter to them at the end of October, Postl and Craig were also disturbed by it. It was clear to all of them that an external review was necessary. Their intention was to have Lindsay conduct this review.

The letter, however, should have led Blanchard to question the wisdom of allowing the program to remain at full service. It would have been the proper thing to immediately speak to Wiseman and to have asked for his views on the issues it raised. Blanchard also should have distributed it to the other department heads immediately, instead of waiting until the end of October to show it to them.

SEPTEMBER 27—THE CASE OF JB

On September 27, JB, a six-month-old child, underwent surgery to close a ventricular septal defect and an atrial septal defect, and to ligate a patent ductus arteriosus. Surgery was complicated because she suffered from pulmonary hypertension.

In this operation, Odim was assisted by both Hamilton and Hancock. According to Wong, who provided the anaesthetic, the operation was marked by problems with cannulation.

Wong testified that the patient ran into trouble during insertion of the venous cannula. At that point, he said, there was a significant loss of blood and a drop in blood pressure. He attempted to raise the blood pressure by treating JB with medication, but was becoming worried that JB would arrest before she could be placed on bypass. "So I said to the surgeons, if you don't get this child on bypass now, this child is going to die." (Evidence, page 19,923) Wong testified that the surgical field was full of blood, the team had initiated sucker bypass and the patient had not been cannulated. Shortly after that, the child was successfully cannulated and the operation proceeded.

In their evidence Odim, Hancock and Hamilton said they could not recall problems with cannulation in this case. The PICU resident's notes corroborate Wong's version of events, in that they indicate that, on transfer of the patient to the PICU, Wong told her that there had been difficulties with cannulation and sucker bypass had been instituted.

JB was discharged on October 18, 1994.

THE SEPTEMBER 28 MEETING OF THE WISEMAN COMMITTEE

The Wiseman Committee met on September 28. Much of the meeting was spent discussing post-operative care. Preliminary acceptance was given to what was referred to as the 'One Team – One Location Model.' Under this model, post-operative care would be provided in a single setting by a team that allowed the neonatal intensive care unit staff to participate. Further meetings with the heads of the PICU and the NICU, along with the respective nursing officials, were recommended.

According to the minutes as well, a number of cases were discussed, including one death (the Tena Capili case) and the ML case, in which the child was taken to the ICU in critical condition and had made a slow recovery. There was also discussion about the cancellation of a case, accompanied by a disagreement between those who thought that the program should take on all cases and those who wished to take a more conservative approach. The other issue of longstanding dispute discussed at this meeting was the treatment of post-operative bleeding. As in the past, committee members did not resolve their disagreement; nor did they agree on a particular plan of action on the matter, other than to treat all cases post-operatively in one ICU setting.

Youngson had prepared some notes on the Tena Capili case and had provided them to Wiseman before the meeting. At the end of the meeting, Wiseman pushed Youngson's notes forward on the table, to let her know that she should speak then if she wished to address the case. Youngson testified:

> I just shook my head.
>
> Because by that point in time, there was just no way I was going to say anything any more. I had seen what happens, I had seen some kind of unpleasant things at that meeting, or heard of unpleasant things happening at that meeting, and there was no way at that point in time that I was going to speak out any more. (Evidence, page 8,554)

The fact that Youngson did not speak out at this meeting about the Tena Capili case is an indication of the degree to which the nurses had been silenced by the review process.

SEPTEMBER 30— THE MEETING OF DEPARTMENT HEADS

On September 30, Postl met with Blanchard and Craig. They provided him with a briefing of the history of the Pediatric Cardiac Surgery Program in 1994.

Later that day Postl wrote to Wiseman, asking to see a copy of the case reviews that had been undertaken by the Wiseman Committee (Exhibit 19, Document 257). On October 21, Wiseman responded that there had been no detailed minutes or records concerning individual cases.

> The review was carried out specifically to look for problems and to look for common themes with respect to problems which had been encountered.
>
> The individual case reviews would occur at the Mortality Review Committee, both at the College and hospital level. I believe these are subject to the Evidence Act and are essentially not available.
>
> I can supply you with a list of cases and the associated mortality attached to that list which comprised the initial experience. This perhaps will be of some assistance. (Exhibit 19, Document 263)

This response once more underscores the inadequacy of the committee process. The committee had been mandated to look at the underlying questions of mortality and morbidity; yet, after recommending a return to full service, it had no records that could be shared with Postl. It is to Postl's credit that he expected that there would be case reviews and that he sought to familiarize himself with them. It should be noted that Wiseman's response (which came three weeks after Postl's request) would have left Postl with the erroneous impression that the committee had produced no documentation.

On the same date, Postl also wrote to Boyle, asking for an update on issues relating to pediatric cardiac surgery. Boyle never responded in writing to this request. However, Postl said that he spoke with Boyle about the issue a number of times and was made aware that nursing staff still had problems with the program.

Postl also testified that, as part of his orientation that autumn, he spoke with Giddins, who as acting section head for pediatric cardiology reported to him. Neither Ward nor Giddins expressed concerns about the program's ability to provide full service. Kesselman informed Postl that he was satisfied with the workings of the Wiseman Committee. Postl also spoke about Odim to Hancock, who told him that he was performing very well.

During the fall, Postl became involved in discussions with both Seshia and Kesselman about the possibility of centralizing post-operative care for pediatric patients who had undergone open-heart surgery.

Seshia testified that the NICU staff did not believe there had been any increased morbidity or mortality as a result of any post-cardiac surgery children being treated in the NICU. However, she said, the NICU staff recognized that the interests of the patients were paramount. Since it was the surgeon's wish to have all the patients treated in the PICU, and since there was a low volume in the NICU, she said "it made sense to have them all looked after in one place by a smaller team of individuals." (Evidence, page 33,514)

On September 30, Seshia met with the NICU staff to discuss the amalgamation of post-operative care of pediatric cardiac surgery patients. At that meeting the NICU staff gave general approval to the proposal.

THE END OF SEPTEMBER: THE NURSES ARE DISTRESSED

By the end of September, many of the nurses were once more disturbed and distressed by the operation of the Pediatric Cardiac Surgery Program. Joan Borton, a nurse clinician with the VCHC, was so troubled that she sought to limit her involvement with the parents whose children were being treated at the VCHC. Her lack of confidence in the program increased when she overheard Odim and Giddins discussing a recently completed operation, with Odim expressing surprise to discover that the child's anatomy was not what he had expected.

She also testified that in September she spoke with Kesselman and concluded that he had doubts about the program as well.

> Because the comment that I remember him making was that none of his family or his friends would be done at Children's Hospital at this point in time. I said, yes, but, Murray, that's what I have a problem with, if we wouldn't allow our own children to be done in this hospital, why do we allow other people's children to be done? It should be the same.
>
> *Q:* His response to your comments?
>
> *A:* He nodded his head. He didn't verbally say anything after that. (Evidence, pages 18,233–18,234)

In his testimony, Kesselman had indicated that he was satisfied with the Wiseman Committee procedure and its outcome. He was not questioned about this conversation with Borton.

Donna Feser, a senior PICU nurse, testified that the PICU nurses were not informed about the decision to take on high-risk cases in the autumn. They could, however, tell that there was a change from the types of cases that were being scheduled. This gave rise to considerable anxiety among the nursing staff, since they expected high-risk children to return from the OR in poor condition.

Feser gave this description of her memory of the fall of 1994.

> For me that's when everything started to blend together that fall. My anxiety level got to the point, from my perspective I started to get into a position where I was, I would call it a functional role. I was having such a difficult time dealing with all of the emotions from what I was seeing in the unit, the sick kids were coming out with so many complications and so many—especially all of the open chests and all of the pacemakers that were, extra pacemakers that we were seeing. We were seeing kids that were really very, very sick, much sicker than we were used to seeing from the previous program.
>
> I mean, like I said, it got to the point where I really had a difficult time in even wanting to come to work, because I really felt, every time I came to work I was feeling quite sick. It was very difficult to

> see these kids struggle, struggle to survive, see these parents suffer, you know, see them, you know, bring their children into us and, you know, trusting us and hoping for the best. And you know, there were many deaths that we had a very difficult time dealing with. (Evidence, pages 30,002–30,003)

She said that, in the past, she would not expect a child with a VSD to arrive in the PICU with an open chest, with excessive bleeding, with clots, or with a need for a pacemaker, but that was the way they arrived during the period when Odim was operating.

Youngson testified that she also attempted to change her role to limit her contact with parents at about this time. She had already decided that she was not going to be involved in pediatric cardiac cases after February 1995, if things continued as they were. She had even considered telling parents to "take your baby and run." (Evidence, page 8,779) She found it hard to take the children from the arms of their mothers and carry them into the operating room.

When asked why she did not warn parents away from the program when she had so many doubts about it, she said:

> Well, first of all, when I see these parents, we are literally at the door of the operating room. They have gone through all of the pre-op teaching sessions, they have gone through all of the stress of preparing themselves for this particular event, and I can't imagine anything could be more stressful for a parent than something like this. I could sort of paint a picture of what it would be like if I had gone out to this parent and said, stop, you can't do this, take your baby and run or whatever. I wouldn't have said it like that, but just don't take this child, I don't want to take your child in.
>
> What would have happened then would have been that all hell would have broke loose. They would have called Dr. Odim, they would have called Dr. Wiseman probably, called the director of nursing up. There would have been this big group of people come to this, wherever we were, waiting room or wherever. I would have been very upset by then, probably crying. There would have been Dr. Odim and Dr. Giddins and whomever, calm, cool, collected. I would have looked like an over emotional, almost crazy person. You know, they would have just thought, they would have talked to the parents, they would have said, maybe this nurse is just overreacting, maybe she is over emotional.
>
> As a parent, I think it would depend on the parents, would they have listened? Maybe they would have backed off, maybe they would have said let's wait another day and rethink this. Maybe they would have listened to Dr. Odim, listened to Dr. Giddins, whom they knew and had met several times before, and don't forget they are just meeting me for the first time at that point. I don't think it would have done any good. I think perhaps I could have saved that one child, and I still think about that from time to time. But there would have been more kids come in, the next kid—I would have been out of there. I would not have had that job any more. I would have been out of there. The program would not have stopped, and there would have been more kids come in the next day or the next week. And nothing good would have come out of that. (Evidence, pages 8,779–8,780)

Given that there is a growing expectation that nurses act as patient advocates, and take an oath to conduct themselves with honesty and integrity, safeguard the quality of nursing care and protect patients from unsafe, incompetent or unethical care, some might argue that Youngson should have spoken to the parents about her concerns.

However, as she indicated, she was in a very difficult position—and was essentially torn between her professional responsibilities and her growing moral qualms. She and the other OR nurses cannot be faulted for their actions. While nurses are expected to act as advocates, the expectation is that they restrict their actions to those areas that they are professionally competent to judge.

Secondly, there is an expectation that they would take their concerns about a fellow medical professional to that professional first. If the concerns continue, the expectation is that the nurse would then speak with a supervisor, who would then deal with the matter or move the matter further up the line of responsibility. If this fails to bring about a satisfactory resolution, the nurse would then be expected to report the matter to a professional licensing body.

When a matter lies outside a nurse's specific area of expertise (nursing), the general expectation has been that the nurse would not take concerns directly to patients or the parents of patients. When Youngson had raised any concerns with Odim, she had not found him receptive. She had also raised her concerns repeatedly with her own supervisors.

They, in turn, had acted appropriately: Karin Dixon had brought the concerns to the attention of Isobel Boyle, and Boyle in the spring of 1994 had brought the concerns to the attention of Bishop, Wiseman and, according to Boyle's testimony, the responsible vice-president, Susan VanDeVelde-Coke. Once the Wiseman Committee process had moved the program back to doing high-risk cases, Youngson and other nurses had good reason to believe that their voices would not be heard. While they continued to raise their concerns with their supervisors, the ineffectiveness of that process drove Youngson to consider taking her concerns to the broader public.

To recap: within weeks of the program resuming full activity, it appears that the surgeon had no faith in the anaesthetists, that many of the anaesthetists were alarmed by the events in surgery and that some nurses were concerned about the morality of their continued involvement with the program.

Whistle-blowing

There is a considerable body of material about the phenomenon of 'whistle-blowing' in medicine. In this context, whistle-blowing refers to the situation where a person relays information to someone outside the regular reporting process of a hospital in order to reveal something that has happened, in an attempt to bring about a more public investigation. Obviously, with the issues of confidentiality and privacy that go with medical treatment, hospital personnel cannot easily speak publicly about how a particular patient or group of patients have been treated or are being treated in a particular facility, by a particular doctor, or within a particular medical program. As well, with hospitals having put in place processes for staff members to relay their concerns about treatment, it is reasonably expected that if the proper process is used, proper steps will then be taken to address legitimate concerns.

There may be reasons why someone may become frustrated. The process may be too slow. The concern may not be accepted for reasons that are not appropriate, for example, a doctor's view being given greater weight than a nurse's, simply because of differences in status. (It must be kept in mind that doctors largely control review processes within hospitals.) For nurses, there is the additional matter of overcoming the historical burden of silence expected of their profession. Nurses who speak out, particularly in a manner that is critical of doctors, are still seen as committing an act of disloyalty, regardless of the legitimacy of the concern. Alternatively, the hospital may not be interested in investigating the issue, perhaps for reasons of legal liability.

Little protection exists for 'whistle-blowers' in the Canadian medical system, particularly if the system does not validate their complaints. Given the outcome of the Wiseman Committee process, Youngson had good reason to fear that her complaints would not be validated by the hospital, even if she went public with them. The problems that confronted Youngson and the other nurses in getting heard do not reflect a lack of professional responsibility on their part; rather, they appear to reflect the historically subordinate role that the nursing profession has played in our health-care system.

The issue of whistle-blowing was raised with the Inquest as something that required redress in Manitoba's medical-care system. There does appear to be merit to that view. In this case, none of the persons involved actually went outside the processes available to address the concerns they had. While those with concerns appear to have spoken with all those in positions of authority who they could identify, none of their actions came close to involving people who were outside the very institution that had a responsibility to do something about those concerns. However, the concern that Youngson had about going to speak to authorities outside the hospital and the personal and professional risk she ran on doing so, point to the need for change in this area. Chapter Ten contains recommendations for changes to protect whistle-blowers.

THE CASE OF ERICA BICHEL

ISSUES

Erica Nicole Bichel died on October 4, 1994, after undergoing a first-stage Norwood procedure. Her case gives rise to a number of issues:

- Should the Winnipeg team have attempted another Norwood procedure, given its recent history and its level of experience?
- Should Erica have been transferred out of Winnipeg?
- Should the operation have taken place before October 4?
- Were her parents provided with sufficient information to allow them to give informed consent to the procedure?
- Was Erica given adequate myocardial protection?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Erica Bichel was born at the Victoria General Hospital in Winnipeg, on Thursday, September 29, 1994, at 2301 hours. The third daughter of James and Judith Bichel, Erica had a normal delivery at only 36 weeks gestation.

On her admission to the nursery at the Victoria General at 0010 hours on September 30, the initial nursing assessment found Erica to be alert, active, with pink colouring and in no respiratory distress. There was no detectable heart murmur. Over the next 24 hours, however, as her ductus arteriosus began to close, Erica's condition started to deteriorate. Her colour became dusky, her respiratory rate increased and she had trouble feeding. On October 1, the Neonatal Transport Team transferred Erica to the HSC, arriving at 1651 hours. This was just over 40 hours after she had been born.

Erica was admitted to the NICU at 1700 hours. By 1930 hours, she was pale and mottled, with increased duskiness. Her heart rate was rapid at 178 beats per minute, her blood pressure had dropped and her oxygen saturation had fallen. A chest X-ray revealed her heart size to be at the upper limits of normal and the findings suggested pulmonary edema.

She was diagnosed with:

- tricuspid atresia
- an atrial septal defect
- anomalous pulmonary venous connection
- transposition of the great arteries
- a hypoplastic aortic arch with coarctation
- a small VSD
- severe hypoplasia of the right heart.

The ductus arteriosus had closed, but reopened after Erica had been given prostaglandin.

Tricuspid atresia meant that Erica lacked the normal opening (or tricuspid valve) between the right atrium and right ventricle. The large atrial connection denoted a hole in the wall between her left and right atria. The pulmonary veins usually connect to the left atrium individually; however, in this case they came together as a single vessel before connecting to the atrium. As a result of the transposition of the great arteries, Erica's aorta and pulmonary artery were each connected to the wrong ventricles. Because of the coarctation of the aorta, this blood vessel was pinched and underdeveloped. The pinching restricted blood from flowing from the heart to the rest of the body. In Erica's case, the right ventricle was severely hypoplastic (underdeveloped). This left her reliant on her left ventricle for all of the heart's pumping action to the body and to the lungs. It should be noted that she also had a hole in the septal wall between her ventricles.

The presence of an underdeveloped right ventricle and transposition of the great arteries meant that Erica had functional, as opposed to a true, hypoplastic left heart syndrome.

In their report for this Inquest, Duncan and Cornel concluded that Erica's difficulties had been properly diagnosed. If she was to survive, it was necessary that surgery take place within days of the diagnosis.

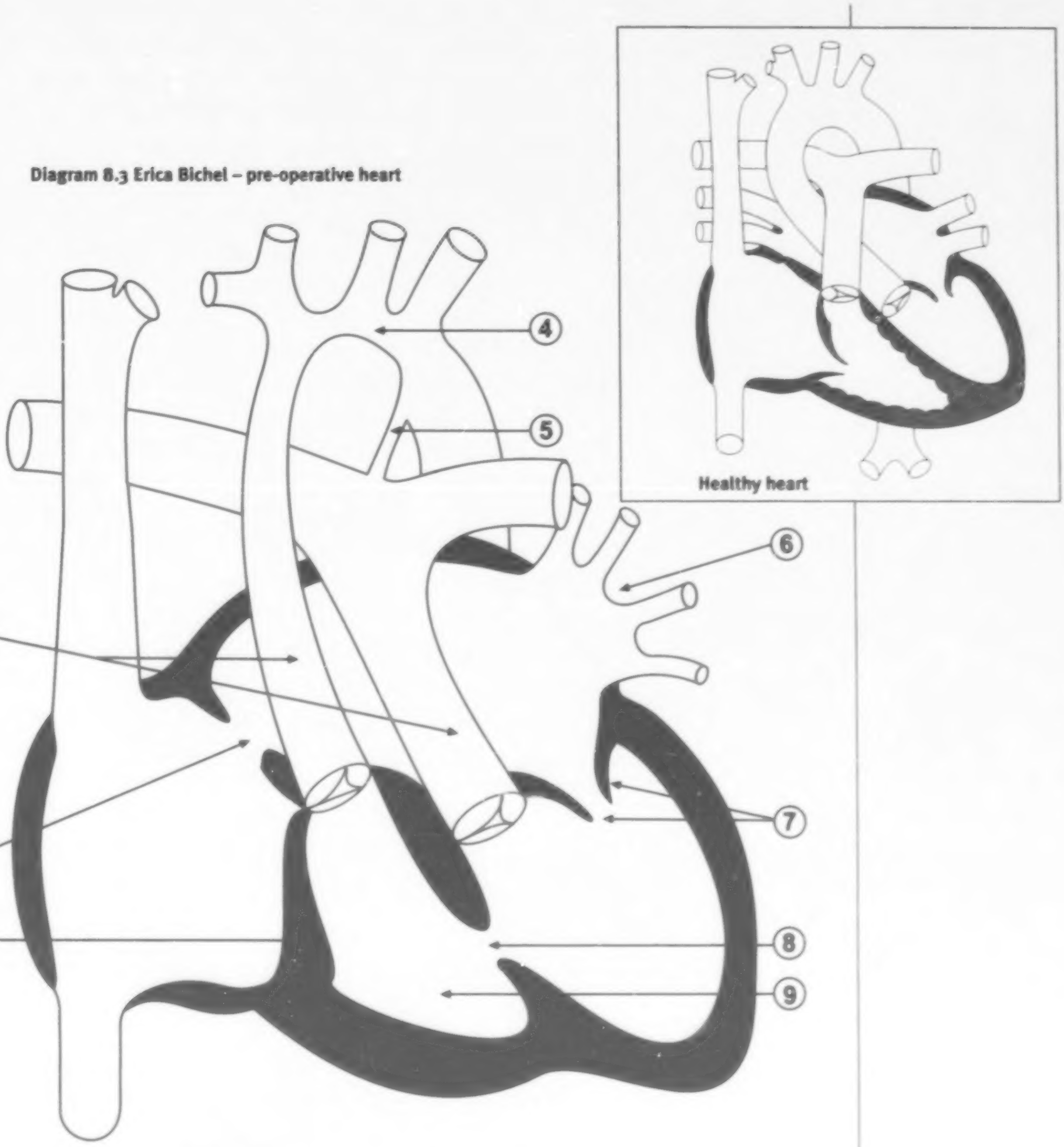
THE DECISION TO OPERATE

Dr. Cameron Ward examined Erica on October 1 and found her to have palpable but weak pulses in her arms and legs and an enlarged liver. These findings indicated poor blood flow from the heart to the body and congestive heart failure. In his testimony, Ward described Erica as "catastrophically unwell by that stage." (Evidence of Dr. Ward, page 70) He concluded that the only treatment would be a type of Norwood procedure.

Ward treated Erica with prostaglandin to keep her ductus arteriosus open. He inserted an endotracheal tube and instituted mechanical (artificial) ventilation. He also treated her with a diuretic, Lasix, to keep her lungs clear of fluid.

Erica's heart, which had only one working ventricle, faced a number of very difficult challenges if it was to get oxygenated blood to all the parts of her body. The coarctation and the transposition created numer-

Diagram 8.3 Erica Bichel – pre-operative heart



1 – Transposition of the great arteries
2 – Atrial septal defect
3 – Tricuspid atresia
4 – Hypoplastic aortic arch (with coarctation)
5 – Patent ductus arteriosus
6 – Confluent pulmonary veins (diagnosed as anomalous pulmonary venous connection)
7 – Dysplasia of mitral valve
8 – Ventricular septal defect
9 – Hypoplastic right ventricle

ous problems, in terms of pressures and blood flow. To help the function of her single ventricle, Erica was given dopamine, a drug that improves the heart muscle's ability to pump. However, the tasks that her heart was required to undertake actually weakened or compromised it. As a result, she required ever-increasing doses of dopamine.

As noted in Chapter Two, there are only three options for a child with the problems that Erica faced: 1) a heart transplant, 2) a Norwood procedure as the first step in a series of staged repairs, or 3) comfort care until the child's heart fails. In Canada, transplants for patients like Erica were quite uncommon at that time.

This would be the second Norwood-type procedure that the team performed in 1994. Giddins testified that, while Erica was smaller than Daniel Terziski, who had undergone the first Norwood-type procedure, the fact that the team was "that much more integrated would potentially be in her favour." (Evidence, page 4,048) Giddins's view that the team was "that much more integrated" seems out of touch in the face of the evidence, which suggests a deepening rift existed between Odim and the anaesthetists as well as between Odim and the nurses.

Giddins testified that he approved of the decision to undertake the Norwood. He saw no reason to canvass the team members to see if they felt the program was ready to handle this case. Considering the issue of case selection that the anaesthetists had raised during the Wiseman Committee process, and the tensions within the team, this also seems to have been a particularly unwise decision.

Ward spoke to Erica's parents that evening. He testified that he told them that, unless Erica underwent a Norwood repair, she would die. He also indicated that a Norwood itself was an extremely risky procedure that would leave Erica functioning with half a heart. According to Judith Bichel, Ward told them that Erica only had a 30 per cent chance of surviving surgery, adding that the surgeon would probably give the family better odds. In his testimony, Ward said that he could not recall any consideration being given to transferring Erica out of province. He testified:

> I don't think that transporting this child would have been a great option anyway. Transporting any sick neonates to another centre when they're requiring intensive care is always to the patient's detriment, and the only question is whether the detriment of that patient overcomes any—any potential benefit that you get from moving to the other centre for the surgery and/or post-operative care. (Evidence of Dr. Ward, page 78)

Ward was also asked about if he had doubts about whether or not the team should be undertaking this operation in Winnipeg.

> What was my view? I guess that at that stage I was new to the program. I didn't really have a perspective at that stage as to whether I thought the surgery should or should not be performed there. My own honest opinion was that this child would likely die wherever it was operated on. (Evidence of Dr. Ward, page 79)

Odim saw Erica that evening at 2250 hours and concluded that a type of Norwood procedure was required.

On Sunday Odim spoke with Erica's parents about her condition and diagnosis. He was asked what he told the parents.

> I presented those options to the Bichel family, and presented the options in Canada, really being doing nothing or a Norwood operation. And at the time the child had just been resuscitated, and the general consensus, as was my consensus, was that this was going to be a very high risk venture, even more so than usual because of the requirement for resuscitation and drug therapy. (Evidence, page 25,649)

Judith Bichel testified that Odim had explained the repair and its risks to her and her husband. He told them that Erica's chances of survival were fifty-fifty. She said that when her husband had asked if Odim had performed this procedure before, Odim had told them he had not, but that he had assisted in such operations. Why he did not tell them of his experience with the Norwood procedure in the Terziski case is open to speculation. Judith Bichel said that they were not told of any alternatives to this type of procedure; nor was a transfer to another centre suggested.

Odim testified that he could not recall if he spoke with the Bichel family about his own experience with Norwood procedures. Odim was asked if it was standard procedure to discuss either his experience with a lesion or the institution's experience with the lesion with parents.

> It was not—it varied case to case, it wasn't a standard procedure to talk about my particular experience or the number of cases that I had done. It came up from time to time with certain families who queried, but it wasn't a standard approach.
>
> *Q:* Again, the way it came up was if they asked, is that correct?
>
> *A:* Usually, yes.
>
> *Q:* Was there any discussion about the possibility of doing this surgery in another centre?
>
> *A:* Not that I can recall.
>
> *Q:* Okay. So you don't recall considering that option?
>
> *A:* No, I don't. (Evidence, pages 25,653–25,654)

It was pointed out to Odim that the decision to undertake this very risky procedure was being taken less than a week after he had sent Blanchard a letter indicating his dissatisfaction with the program. He was asked if there was not a contradiction between the feelings expressed in the letter and the decision to undertake a Norwood.

> Certainly the members of the team throughout the year had discussed issues of Norwood operations. It was discussed during the Wiseman committee, and there really wasn't any indication that team members felt that we should not be embarking upon offering this as a last ditch effort for families.
>
> So at the time this procedure was contemplated, certainly the general consensus was this child was too sick to go anywhere. And secondly, if anything were to be done, it would probably have to be done here in Winnipeg. And the families were presented that option, or this family was presented that option, albeit very risky. (Evidence, page 25,655)

Cornel was asked if he thought that it would have been possible to transport Erica to another centre. He replied:

> I can't really comment on the first day, but after that she was, all the time she was in hospital I think she was being managed pretty well, and I think she was deteriorating constantly. I don't think she could have, honestly. (Evidence, page 44,874)

When asked if it would have been difficult to transfer Erica, Dr. Walter Duncan testified:

> Yes, I think transfer would have been quite hazardous. Again, you can argue it may not be as hazardous as performing surgery. I think that some centres in Canada would not do this type of surgery, given the information. (Evidence, page 41,446)

In a surgical note that he made at the time, Odim wrote that he reviewed all of the options including non-surgical and palliative. He also wrote:

> As this is not a true HLHS [hypoplastic left heart syndrome] she falls into a more favourable category of child undergoing the stage one Norwood procedure en-route to a Fontan. The risks and attendant post-operative problems have been discussed with the family in detail. They seem to understand and give their verbal and written consent for operation. (Exhibit 3, page BIC 36)

Odim was questioned about his comments that Erica was in a more favourable category, particularly in light of his statement that hers was a very high-risk case.

> [H]er single ventricle was a left ventricle as opposed to a right ventricle in true anatomic hypoplasia of the left side of the heart. And the experience and data seems to indicate that if you have a single ventricle, many a times the left ventricle seems to perform a little better, because it is more programmed embryonically and genetically to do the high pressure systemic work, as opposed to the right ventricle which has a different shape and a different genetic program, just to do pulmonary work. (Evidence, page 25,652)

Odim indicated he had planned for a period of treatment and then surgery on Tuesday morning. The hope was that controlled ventilation, prostaglandin and dopamine would stabilize Erica. However, the evidence shows that she was never in stable condition before surgery.

After the operation, Odim wrote a note to Erica's doctor, Dr. Matthew Lazar. In the letter, Odim wondered if an earlier repair would have made a difference in the outcome (Exhibit 3, pages BIC 21-22). However, none of the witnesses to this Inquest were critical of the decision to attempt to stabilize Erica's condition before surgery.

PRE-OPERATIVE STATUS

Erica's blood pressure and central venous pressure (CVP) dropped all day on October 2, requiring an increase in the use of dopamine. Her urine output was good. She had mild pulmonary edema, for which she was treated with a diuretic. A chest X-ray showed improved ventilation of the left lobe of her lung, when compared with an X-ray taken that morning. However, there was a suggestion of collapse in the right lung and the presence of a small amount of pulmonary edema.

That day the Bichels gave verbal consent to proceed with the operation on Tuesday, October 4, 1994.

Erica's colour remained pale and dusky and she was jaundiced, a sign that her liver was failing. She was given a drug (Pavulon) to relax or weaken her muscles. This was done to decrease oxygen consumption by the muscles and make mechanical ventilation of her lungs easier. Erica required many changes to the settings of the ventilator during the day, to accommodate her declining oxygen saturation.

A DESPERATE SITUATION

On October 3, Erica's condition remained extremely unstable. Large amounts of clear yellow secretions were suctioned from her endotracheal tube and her mouth. In the evening, she had decreased chest expansion problems and an increase in the amount of carbon dioxide in her blood, with a resultant need for increased ventilation. The prostaglandin was also increased, with the result that her femoral pulses felt much stronger.

Erica's blood pressure dropped, but then improved with increased doses of dopamine. On admission to the HSC, she had been treated with five micrograms of dopamine per kilogram of body weight per minute. By the time she went to the operating room, she was receiving 20 micrograms per kilogram of body weight per minute. By that point, she was said to be 'inotrope dependent'. In other words, without the dopamine, Erica's heart could not have continued pumping. As Odim testified, this reduced her chances of surviving the operation. He said that from Saturday, October 1 onwards, her condition worsened:

> The child then deteriorated over the next days to the point where the child was on a significant amount of inotropic agents and it became very difficult at that point because we all acknowledged that, boy, this is high risk. But it is sometimes very difficult, once you have made plans with the families, to then remove that last straw of hope two hours before going to the operating room. And it is a difficult decision, and we do think about it. (Evidence, page 25,657)

Odim was asked if he had discussed with the family the fact that what had been a high-risk case had become even higher.

> Again, I don't remember. Except I remember coming in early in the morning to see the child and being amazed that a couple of hours before surgery, three or four hours before surgery, that we are on such massive doses of dopamine. And I certainly alerted the team members that many patients, most patients don't come out of the operating room when you go in. And I don't remember whether the family was there or I was able to get a hold of the family to present this to them. But we had already made plans to go to the operating room, and they had already told us to do the best we could for Erica. And you are right, it is difficult for a surgeon at the last second to pull out the rug of hope from underneath a family. (Evidence, page 25,658)

Both Cornel and Duncan were questioned about whether or not Erica had any chance of surviving surgery, given the level of her dependence on inotropes. Duncan suggested that in some cases, a child in that condition would not be taken to surgery. He testified:

> Well, I think if the child requires that amount of support prior to doing a long operation, which leaves you with an imperfect result in the end, even if it's perfectly done, likelihood of survival is minimal.
>
> Again, I have stated this had, that there may be pressures brought to bear on the team and the surgeon from the family to do anything, despite how desperate things may appear. And there is often pressures in that regard, but this child anatomically, looking at the specimen, the actual surgical techniques and anastomoses that were created appeared fine. I don't see any difficulty with anything that was done. But the heart muscle just ran out of gas. (Evidence, pages 41,444–41,445)

In his testimony, Cornel stated:

> That probably of itself, the requirement for a large dose of dopamine leading up to surgery probably means that the risk was almost prohibitive of surgery, and I would probably not do a case under those conditions. But I don't mean to imply that it is wrong to try, but I think I've tried enough of those desperate cases to not want to do it anymore. (Evidence, page 44,869)

In discussing Erica's pre-operative status, Cornel wrote that:

> This infant was never stable prior to surgery and the myocardial compromise must have been severe. The risk of surgery under these conditions is extremely high. I do not criticise the team for trying. (Exhibit 353, page 56)

Duncan commented in his report:

> One wonders about the wisdom of an inexperienced surgical team attempting Norwood repairs, but it sounds as if the child would have died anyways before transfer might have been effected. (Exhibit 20, document 363, page 5)

In their joint report Cornel and Duncan wrote, "This was a very high risk procedure in a child already requiring potent drugs to maintain blood pressure prior to surgery." (Exhibit 354, page 12) They indicated that in some locations, these levels would be considered so high as to stop the surgeon from undertaking the procedure.

Soder, however, said that in 1994, at the Izaak Walton Killam Hospital for Children in Halifax, "I'm reasonably certain we would have encouraged the parents to go ahead with surgery with this anatomy." (Evidence, page 44,172)

PREPARATION OF THE NICU

In her testimony about the Terziski case, Debra Armitage, a senior NICU nurse, said she felt that there had not been sufficient pre-operative communication from Odim regarding Daniel's post-operative care. In his testimony, Dr. Heinz Reimer said that the NICU staff did not appear to fully appreciate the severity of Daniel's post-operative condition.

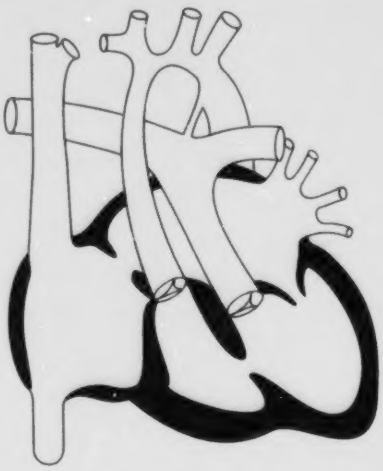
Despite that experience, before the operation in Erica's case, Odim did not give any special instructions to the NICU staff. He testified that:

> [I]t was the same unit that was taking care of this patient before we went to the operating room. So the need to advise them of this patient was really moot. They had been managing the patient and we had discussions during that time interval. So, there was no extra preparation above and beyond the usual things that we talk about in terms of managing these kids. (Evidence, page 25,659)

THE OPERATION—OCTOBER 4

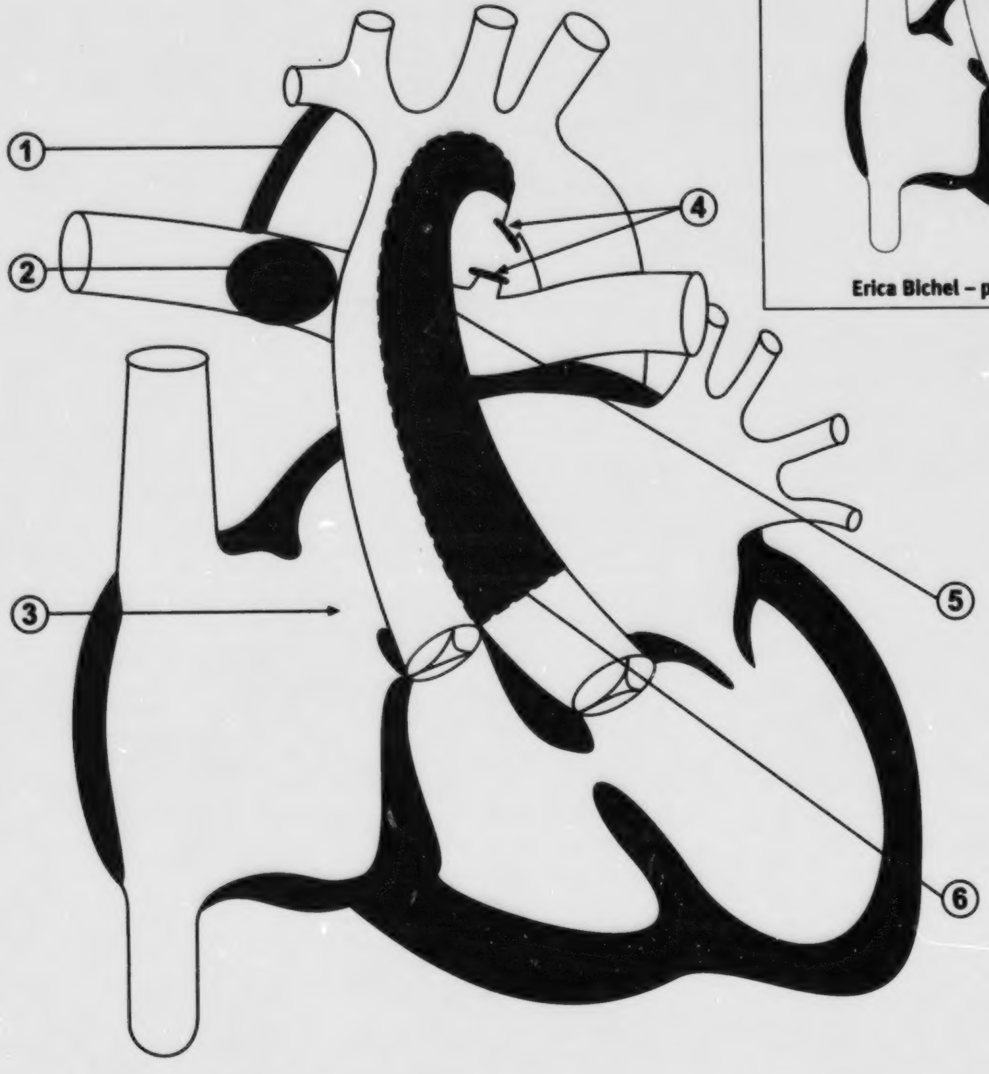
In the early hours of October 4, Erica underwent a modified Norwood Stage I procedure that included

- ligation and division of a patent ductus arteriosus; (This is a surgical closure of the ductus arteriosus.);
- atrial septectomy; (This involves removing the septal wall between the two atria.);
- aortic coarctectomy; (This involves removing the pinched section of the aorta.);
- insertion of a right Blalock-Taussig Shunt; (In this procedure, a small tube or shunt is placed between the innominate artery and the right pulmonary artery. The innominate artery is one of the three arteries that branches out of the arch of the aorta.); and
- aortic homograft augmentation of the aortic arch and main pulmonary artery to aorta bypass, creating a neo-aorta. (This procedure involves building a new aorta by connecting the pulmonary artery to the coarcted aorta and using homograft material to expand the size of the artery. When this is accomplished, the oxygenated blood returns to the left atrium through the mitral valve, enters the single



Erica Bichel – pre-operative heart

Diagram 8.4 Erica Bichel – post-operative heart



1 – Modified right Blalock-Taussig shunt

2 – Pericardial patch at confluence of right and left pulmonary arteries where trunk of pulmonary artery was disconnected

3 – Atrial septectomy

4 – Ligation and division of ductus arteriosus

5 – Aortic coarctectomy and homograft augmentation of ascending aorta and arch

6 – Division and anastomosis of pulmonary artery trunk to ascending aorta

ventricle and is pumped out the new aorta—the former pulmonary artery—and is distributed to the rest of the body.)

Consulting witnesses concluded that this was the appropriate repair for a child in Erica's condition. The operating team is set out in the accompanying chart.

TABLE 8.3: Persons involved in the operation on Erica Bichel, October 4, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	B.J. Hancock
Anaesthetists	H. Reimer, J. Doer (resident)
Scrub nurses	C. Youngson, S. Scott, C. Weber
Circulating nurses	C. Weber, W. Yakinchuk, B. Zulak
Perfusionists	T. Koga, C. McCudden

TABLE 8.4: Length of phases of the operation on Erica Bichel, October 4, 1994

Phase of the operation	*Time taken*
Induction	1 hour 40 minutes
Bypass	3 hours 31 minutes
Total circulatory arrest	1 hour 40 minutes
Total surgical time	7 hours 15 minutes
Total operating-room time	9 hours 40 minutes

In his report, Cornel commented that, at one hour and forty minutes, the period of TCA was very long. Odim was questioned about the length of the procedure. He gave the following response:

> That it was long, and as I said, we were putting this homograft. Many a times in the hypoplastic left heart syndromes, you have varying degrees of smallness of the aorta, and this child had a completely diminutive aorta due to the arch, and distally there was a coarct. So the entire area was two to three millimeters and had to be filleted open in the back, and then we had to rebuild that. The tissues were friable. The child had been on inotropes for two or three days and there was a lot of edema in the tissues. So from the technical point of view, it was a difficult type of a Norwood, given the anatomy. (Evidence, pages 25,669–25,670)

The issue of cardioplegia

Erica's myocardial protection included deep (or profound) hypothermia with cardiac arrest. Hypothermia is a reduction in the central or core temperature of the body below 36 degrees Celsius and is achieved by infusing cold liquids intravenously and packing ice around parts of the body. With deep hypothermia, the patient is intentionally cooled to about 16 to 20 degrees Celsius. This allows the surgeon to stop the heart for about an hour and operate without either the heart moving, or tubing or blood being in the very small operative field.

In his operative report Odim indicated that "30 cc per kgm. of cold cardioplegia was administered through the arterial perfusing cannula." (Exhibit 3, page BIC 56) However, there was no record in the perfusion sheets of any cardioplegia being given. Odim was questioned about this discrepancy.

> I can't resolve it. It is usually my practice with Norwoods to give a dose of cardioplegia. It is certainly possible that that dose was not given or it was aborted at some point, because the aorta was very small in this child. But it is my usual practice to give a single dose of cardioplegia in the Norwood setting. That practice is actually controversial. Some people do not, but I usually do, and I thought I had given cardioplegia.
>
> *Q:* Now, the practice is controversial, maybe you can just elaborate on that?
>
> *A:* It is controversial because there has been no clear benefit of cardioplegia in the setting of Norwood operations, and the use of deep hypothermia and circulatory arrest. Some people have seen a benefit, others have not.
>
> Furthermore, because the aorta is very thin and friable and small, the technique of actually trying to get it into the small aorta and into the coronary arteries is fraught with causing problems. And so for technical reasons, some people rely purely on a deep hypothermia for myocardial protection. (Evidence, pages 25,667–25,668)

Perfusionist Todd Koga testified that, according to the perfusion record, no cardioplegia was given for this operation; nor could he remember any being given. He said that the manner in which Odim would have had to give the cardioplegia (through the arterial perfusion cannula) in such a case would be unusual. According to Koga's testimony:

> Normally it's administered from the [root] of the aorta via separate, not via the main perfusing cannula but via separate cardioplegia needle, and it is usually administered with the cross-clamp in place. (Evidence, page 7,231)

Koga said that he never worked with Odim when cardioplegia was delivered through the arterial perfusion cannula.

In his report, Cornel wrote:

> Cardioplegia was not given. I do not always use cardioplegia with PHCA [profound hypothermia with cardiac arrest] but usually do so and with an already compromised myocardium would be more inclined to do so. This is a comment rather than a criticism. (Exhibit 353, page 56)

In their joint report, Cornel and Duncan wrote:

> We note that only hypothermia was used. However, hypothermia alone may have been a reasonable choice. (Exhibit 354, page 12)

In his testimony, Cornel said:

> In the Norwood operation specifically, administration of cardioplegia is particularly difficult. It would be very unwise to try and put a cannula into the tiny little ascending aorta in a true hypoplastic left heart. Those vessels are difficult enough without any added trauma, and in those cases I would not give cardioplegia.
>
> In a case like this where there is access to the coronary arteries through the aorta, if cooling was proceeding very easily, I was sure that the heart was stable before surgery—I might not give it if I was a little concerned about the aortic tissue, but in a case like this I might have given cardioplegia through the aortic root with a small needle. I might or might not, but it would certainly be something to consider. (Evidence, pages 44,871–44,872)

Taylor was asked if he could determine if Erica had been given cardioplegia during the course of surgery. He responded that he would have expected extensive damage to her heart if she had not received cardioplegia. He went on to say:

> I can only infer from the presence or absence of myocardial injury that there may or may not have been adequate myocardial protection. So I can't say, yes, cardioplegia was given or, no, it wasn't given. All I can only say is, well, she has got a lot of damage, therefore, her protection might not have been optimal. (Evidence, pages 43,234–43,235)

In his evidence, Taylor also said that, while the heart was damaged, he could not be certain as to how much of the injury was sustained before the operation.

The failure to wean from bypass

After the repairs had been completed, Erica was taken off bypass. Shortly thereafter, the pressure in her atrium fell rapidly and Erica's heart stopped. This necessitated a rapid return to bypass.

She remained on bypass for another 15 to 20 minutes. During that time, the team adjusted some of the inotropic medication with which Erica was being treated, and attempted to go off bypass a second time.

This time they were off bypass for approximately 40 minutes. However, her condition deteriorated once more and they returned to bypass. Again the inotropic medication was adjusted and another attempt was made to come off bypass. According to Odim, one of the walls (the anterolateral wall) of the left ventricle was not performing adequately. There was a progressive decline in cardiac function, and eventually Erica lost any heart rate or rhythm.

At this point, the team had to decide whether to stop treatment or put Erica on ECMO. Reimer testified:

> We were dealing with a child whose heart was already failing before the procedure began. It was now continuing to fail, and it was just thought that the chance of her recovering, or her heart recovering, given a prolonged period of ECMO, was quite small. I mean, the risks of instituting ECMO are fairly high in terms of bleeding complications,neurologic complications and so on. And based on things like that, and I think Jonah mentioned something about the experience in other centres with ECMO and children with this, having had this procedure was not good. (Evidence, page 19,074)

After consultation among Odim, Reimer, Ward, Giddins and a neonatologist, a decision was made that ECMO treatment would not be successful. Erica died in the operating room at 1630 hours.

The Bichels had been advised to stay at home on the day of surgery. They received hourly updates from Lois Hawkins throughout the course of the operation. Each time she called, she told them that Erica was doing well. They finally received a call saying the operation had gone well to that point and were summoned to the HSC.

When the Bichels arrived at the HSC, they were told that Erica was still being taken off bypass. They were encouraged to go for a meal. When they returned to the NICU, they were told that Erica had died. They were then taken to a private family room. At Judith Bichel's request, Erica's body was brought to the family. The parents then spoke with Odim, Giddins, Ward and Hawkins.

POST-MORTEM FINDINGS

Phillips performed the autopsy on October 5 in Odim's presence. According to the autopsy, Erica's anomalies had been properly diagnosed and repaired. All repairs were intact and free of attached clot and the Blalock-Taussig shunt was patent.

According to the autopsy report, there was myocardial hemorrhage (bleeding in the heart muscle) with patchy necrosis. The microscopic findings of the myocardium indicated that the necrosis was ischemic (due to oxygen deficiency) and perimortal in nature. In her testimony, Phillips explained that by perimortal, she meant that the damage could have taken place before or during surgery.

The autopsy report concluded that no anatomical explanation for death had been found. In her testimony, Phillips said:

> Knowing what I know now, after going through Dr. Taylor's report, probably the heart and the brain perhaps were damaged before she even went into surgery, and then it was compounded by the surgical procedure, and she was not able to get off bypass. (Evidence, page 42,303)

In his report, Taylor wrote:

> The surgical anatomy in Erica's case appeared satisfactory and her death resulted from the myocardial failure rather than an anatomical complication of the procedure. The heart demonstrated microscopic findings of acute ischemic damage, judged moderate in extent in the single histology slide available. Although this is a limited study, it was from the functional ventricle and is most likely a representative sample of the myocardium, since myocardial damage occurring with repair of congenital heart defects most often occurs globally rather than in the regional distribution of a particular coronary artery branch. The damage identified was not associated with inflammation or reparative changes and could represent injury occurring during the surgical procedure and/or up to a day or so before surgery. (Exhibit 336, page 9.1)

In short, Erica's heart had been damaged by poor perfusion, both before and during surgery. (This should not be taken as a criticism of the service provided by the perfusionists, but as a comment on her overall level of blood perfusion.)

In his testimony, Taylor said he could not determine the degree to which contraction band necrosis was the result of damage that took place before or during surgery. He said he could say with certainty that the heart was damaged before surgery, but could not say for certain if the heart was damaged during surgery.

Taylor noted that the autopsy uncovered signs of neuronal necrosis in Erica's brain. He said this indicated that she had "significant circulatory impairment before her surgery. Whether or not operating on Erica a day or two earlier might have changed the outcome can be speculated upon, however, regardless of the timing of the surgery, I believe that her prognosis would be at best 'guarded,' given the severe nature of her cardiac malformations." (Exhibit 336, page 9.1)

In his report, Hudson indicated that he thought there were four major factors that could have contributed to Erica's cardiac failure. The first was the effects of her pre-existing congenital heart problems. The other three were:

> **Myocardial injury before CPB.** Hypoxemia [This refers to the poor perfusion and saturation that Erica experienced pre-operatively.] was documented before CPB. Hypoxia prior to the obligatory period of aortic cross-clamping and cessation of coronary blood flow could add to myocardial injury

> because the heart would not be in the best achievable metabolic condition just before cross-clamping. In my opinion, by itself, the degree and duration of hypoxia before CPB cannot account for the severe and ultimately lethal myocardial pump failure that occurred. However, it could add to the injury produced by other factors.
>
> **Inadequate myocardial protection during CPB.** The inability to separate from cardiopulmonary bypass without substantial inotropic and vasopressor support suggests that myocardial protection during CPB was not adequate. Of particular concern is the discrepancy between the surgeon's operative note, and the perfusion record. The surgeon's dictated note states that 30 ml/kg of cold cardioplegia was given shortly after initiation of CPB. The perfusion record indicates that no cardioplegia was given. Although hypothermia alone offers some myocardial protection, the diastolic arrest induced by cardioplegia is of greater importance in protecting the myocardium from injury during aortic cross-clamping. ***Whether or not cardioplegia was given to this patient is an important fact that must be established.*** [Italics and bolding in original.] The long duration of TCA would also contribute to myocardial damage.
>
> **Myocardial injury or dysfunction after CPB.** High doses of catecholamine inotropic agents, which this patient required to separate from CPB, can contribute to myocardial injury. However, this is a no-win situation. Without the drugs, separation from CPB is impossible, so the possibility of adverse effects has to be accepted. The severe hypoxia after CPB could also aggravate myocardial dysfunction and injury. (Exhibit 307, page 9.10)

The issue of adequate cardioplegia is vexing and will be discussed below.

In reviewing the case, Cornel wrote that the "myocardial compromise was probably severe before the operation commenced and the inability to withdraw from bypass is not surprising." (Exhibit 353, page 56)

FINDINGS

As identified in the introduction, this case gives rise to the following issues:

- Should the Winnipeg team have attempted a Norwood procedure, given its recent history and its level of experience?
- Should Erica have been transferred out of Winnipeg?
- Should the operation have taken place before October 4?
- Were the parents provided with sufficient information to allow them to give informed consent to the procedure?
- Was Erica given adequate myocardial protection?
- What was the cause of death and was it preventable?

Should the Winnipeg team have attempted a Norwood procedure, given its recent history and its level of experience?

Should Erica have been transferred out of Winnipeg?

Should the operation have taken place before October 4?

These three questions are inter-related and cannot be answered separately. They go to matters at the centre of this Inquest.

- Findings

The evidence presented to this Inquest suggests that the HSC Pediatric Cardiac Surgery Program should not have been looking after all the patients who came through the door in 1994. As has been noted several times in this report, the evidence suggests that the surgeon lacked the skill, experience and dexterity to undertake a number of high-risk procedures.

This was one such procedure. Indeed, the length of time the procedure took is one more piece of evidence suggesting that the surgeon did not have the necessary skills and experience to handle high-risk operations. That being so, there should have been a protocol under which all high-risk patients would have been considered as candidates for referral out of Winnipeg.

Several witnesses raised the question as to whether or not it would have been appropriate to transfer Erica out of Winnipeg. Duncan and Cornel, for example, asked, "Were the options for transfer to another centre provided? Such a transfer might not have been conceivable given the precarious status pre-operatively." (Exhibit 354, page 12)

Dr. Oscar Casiro, an intensivist who treated Erica, did think it would have been possible to transport Erica out of province. It is clear that transfer would have been risky. Furthermore, the evidence suggests that many centres might not have accepted Erica because she was too ill for them to consider operating on her. In the end, transfer might not have been feasible.

However, because the Winnipeg approach was essentially to take all comers, it appears that Ward, Giddins and Odim did not give consideration to transfer. In fairness to Ward, he was new to the program and had been informed that the team was capable of undertaking high-risk procedures.

However, Odim and Giddins were well aware of the problems that the team had been having and of the failure of the previous Norwood. A failure in a single case should not necessarily mean that the program should not undertake similar procedures in the future. However, the difficulties inherent in the Norwood procedure, and its extreme risk, placed it in a category of cases that the program should simply not have been attempting during 1994.

If there was to be no transfer, the only real options were to allow the team in Winnipeg to operate or to arrange for comfort care for Erica until she died. After Erica's death, Judith Bichel said that her family doctor had suggested that Erica would have been a good candidate for a heart transplant. However, this suggestion does not appear to be widely supported by the consulting witnesses to this Inquest. In addition, while it was conceivable that another surgeon coming to Winnipeg from another location could have performed the operation, the logistics of arranging this probably exceeded the time available to the child. Furthermore, there are real problems with bringing an outside surgeon in to undertake high-risk surgery. Advance planning and co-ordination are required.

- Finding

  There is evidence that the planning that went into this procedure was wanting in several respects. Although Erica did not survive to be transferred to the NICU, the evidence suggests that, as with Daniel Terziski, there had not been adequate planning with the NICU as to her post-operative care.

While there are real questions as to whether or not the Winnipeg team ought to have undertaken this operation, the decision to delay surgery for a number of days was legitimate. Erica was very ill when her condition was first diagnosed. It was reasonable to attempt to strengthen her before taking her to surgery. In the end, this strategy failed to bring about the desired results.

Were her parents provided with sufficient information to allow them to give informed consent to the procedure?

- Finding

  Erica Bichel's parents were not told of the program's recent history. The evidence suggests that they were not provided with sufficient information to determine if they had the option of taking their child to another centre for surgery. They were entitled to this information, before giving their consent to having the operation done in Winnipeg. The evidence tends to suggest that Erica's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Was Erica given adequate myocardial protection?

- Finding

  This seems to be a matter of some dispute among the medical professionals who have examined this case. While Odim said that he generally administered one dose of cardioplegia, the evidence suggests that he did not do so in this case. He also said that the administration of the cardioplegia was not always done in this operation in any event, suggesting that even if he did not give any cardioplegia, it was not unreasonable not to do so.

  Taylor and others do suggest that there was myocardial damage, perhaps due to the lack of myocardial protection (which cardioplegia is intended to provide). However, they were unable to say with certainty whether the myocardial damage they found had occurred before or during the operation. Therefore, it is not possible to say with any degree of certainty that lack of cardioplegia led to or caused any of the myocardial damage that the child suffered.

What was the cause of death and was it preventable?

- **Finding**

Erica had a very serious congenital heart condition. The condition weakened her heart in the period before a very lengthy and risky operation and left her heart in a condition where it could not function following the procedure.

In their joint report, Cornel and Duncan wrote:

> This was a very high risk procedure in a child already requiring potent drugs to maintain blood pressure prior to surgery. We believe that this death occurred due to depleted myocardial substrate reserves [The heart was too weakened to be able to continue to function.] as well as potential myocardial preservation problems. (Exhibit 354, page 12)

In other words, they were of the opinion that Erica's heart was too weak and/or damaged to survive this operation. This condition likely precluded any chance of her surviving the operation.

- **Finding**

The evidence suggests that Erica would have stood a better chance of success in the hands of another, more experienced surgeon and surgical team, but whether or not she would have survived (given her pre-operative condition) is impossible to say. She also might have survived if she had been operated on earlier, but that would have to be weighed against the trauma that would likely have been caused to her through transportation to another facility. Given all of the available information, it is not likely that her death was preventable.

OCTOBER 20—THE CASE OF ER

On October 20, the pediatric cardiac surgery team was involved in inserting a pacemaker in a nine-year-old patient named ER. As an infant, ER had suffered from meningococcemia infection. As a result of this infection, it had been necessary to amputate a number of her limbs. The infection also affected her heart's conduction system.

At the pre-operative conference for this operation (which was attended by the surgeon, the cardiologist, the anaesthetist and the intensivist), there was discussion of what should be done if ER arrested before the pacemaker was inserted. It was decided that a transcutaneous pad would be placed on her chest. This would allow the team to use a precordial pacemaker to pace the heart by connecting it to the pads. The pads would make it possible to pace ER without a direct wire connection to ER's heart.

During surgery, ER went into complete heart block. According to Swartz, who was providing the anaesthetic for this operation, the block was in response to the anaesthetic agents she was using. Swartz said that this was a normal side-effect but was also a complication. ER was treated with a variety of drugs, but her heart did not respond, either to the drugs or to the chest compressions that had also been started. At that point, the team requested that the precordial pacemaker be brought from the ICU.

According to Swartz's testimony, the team was not able to properly connect the precordial pacemaker, which had been recently acquired. Swartz testified that it was her responsibility to connect the pacemaker.

> *A* And we tried the external pacemaker, but it didn't work.
>
> *Q* Why didn't it work?
>
> *A* It didn't work because we didn't know—we hadn't attached her leads to the pacemaker. This was the machine that we just acquired within the last week, and we hadn't used it. It was actually in the intensive care unit, not in the OR. So we called for it to come to the operating room, in the meantime we were doing chest compressions, and Dr. Odim managed to get the pacemaker in and we didn't ultimately require the external pacer.
>
> *Q* Okay. So the external pacer was the first one that you tried?
>
> *A* We tried it, but we hadn't hooked it up properly.
>
> *Q* And whose job was it to hook it up?
>
> *A* I will say my job.
>
> *Q* Okay.
>
> *A* So, you know, I wasn't familiar with that pacemaker, so we hadn't put the leads on properly, so we didn't—we ultimately didn't use it and we did get, Dr. Odim did get the pacemaker in and we were able to hook up to that pacer. (Evidence, pages 16,442–16,443)

Eventually, Odim connected a different type of external pacemaker and was able to go on and implant the internal pacemaker. He testified that he was surprised that no one knew how to use the equipment.

> The manuals came out. Ms. Youngson, the head nurse, didn't know how to get the machine working, neither did Dr. Swartz, I believe, who was the anaesthetist and also intensive care unit specialist.
>
> So there was a lot of confusion, and no one really knew how to turn the machine on or to get it to function. (Evidence, pages 25,687–25,688)

Once the pacemaker was implanted, Swartz felt that the patient was properly paced from then on and that the operation was a success.

Odim testified that he had not used the machine in Winnipeg before that event.

> All I know is at the pre-operative meeting, I asked whether there was a machine in existence, because many a times we will use this as backup sometimes if we are able to get it to capture. And I was told that there was a machine in existence. And I said, well, we better have that on hand for this patient, and I wanted the pads placed; and so that was done. But, what surprised me was that none of the senior personnel, or junior personnel, when we needed it, really knew how to work it. (Evidence, pages 25,688–25,689)

ER was discharged on October 25, 1994. However, she died from a cardiac arrest on July 8, 1995.

While Swartz testified that the level of communications was very good during this procedure, it is apparent that it was not very good in the period leading up to the procedure. If Odim's account was correct, it would appear that Swartz should have indicated that she was not familiar with the pacing equipment he wanted to use as a backup. In addition, if Swartz was not familiar with the equipment, she should have reviewed the use of the pacemaker before the procedure.

The situation concerning the failure to be able to use the new pacing equipment certainly speaks to the inability of the team members to address matters of communications directly at this time in the year. While there was an attempt at briefing the team involved in intra- and post-operative care, there was no follow-through in preparation for the procedure.

THE WISEMAN COMMITTEE MEETING OF OCTOBER 17

At the committee's October 17 meeting, considerable discussion was devoted to the issue of transferring the care of post-operative neonates from the NICU to the PICU. While the neonatologists had given their agreement in principle to the idea of all open cases going to the PICU, neonatal nurses were resistant to the idea. They believed that the move represented a lack of confidence in the care they provided.

Seshia informed the committee that several nurses in the unit had developed a post-operative care package, which was to become a guideline for managing such patients in the NICU. She indicated that there were negative feelings about the lack of input from the cardiac surgeon in that process (Exhibit 20, Document 278K).

In discussing the issue, Kesselman said he believed that two bedside nurses were required for these cases, one of whom ought to come from the NICU. It was pointed out that the PICU nurses had some anxieties about providing care to post-operative neonates.

Giddins reported that two high-risk surgical cases had been successfully carried out. The minutes show no reference to the death of Erica Bichel on October 4. Wiseman testified that he could not recall the case being discussed or reported. Odim testified that he could not recall any discussion by the committee about whether or not the team should be performing Norwoods. Odim did say he was aware that Wiseman did not approve of the Norwood procedure being conducted under any circumstances, a view that Wiseman confirmed in his testimony.

The next committee meeting was to be scheduled after a series of meetings between team members and various HSC staff, to deal with the issue of post-operative care. As a result, it did not meet again until December 7.

At some point in the autumn, Blanchard had informally sounded out a number of people about Odim's surgical skills. Hancock told him that Odim's skills were comparable to Duncan's. Dr. Peter Duke, an adult anaesthetist, told him that Odim was comparable to an average adult surgeon, while Hamilton assured him that Odim was fine.

During the autumn of 1994 Isobel Boyle, after discussions with the operating-room nurses, once more spoke with Wiseman and asked him to observe Odim in surgery. She testified that Wiseman indicated that he was not prepared to do so at that time.

Susan VanDeVelde-Coke, the vice-president in charge of both the Department of Surgery and the Department of Anaesthesia, had heard informally from Boyle in the autumn that the nurses were having concerns about the Pediatric Cardiac Surgery Program, as were the anaesthetists. She testified that she had heard that there were concerns about Odim's surgical technique. According to her, Blanchard had passed on Hancock's positive assessment of Odim. In her testimony, VanDeVelde-Coke said she had not known about the May withdrawal of services until February 1995.

THE MEETING OF THE ANAESTHETISTS ON OCTOBER 19

The anaesthetists were still concerned about the surgical results. At their October 19 meeting, (Exhibit 19, Document 262) they agreed on the need for the Wiseman Committee to look at cardiac deaths.

At this meeting, there was also discussion about the length of time it was taking both the Standards and Audit Committee and the Pediatric Surgical Standards Committee to review the deaths in the pediatric cardiac program. Anaesthetic representatives to the committees were to write to those committees to encourage them to expedite their reviews of the cases.

THE DEPARTMENT HEADS MEETING OF OCTOBER 28

On October 28, Blanchard, Postl, Craig and Wiseman met. At this meeting, Postl summarized the discussions he had conducted with the individuals involved in the Pediatric Cardiac Surgery Program.

According to notes taken by Blanchard at the time, Craig said that pediatric cardiac anaesthesia was "remarkably naïve & feel besieged. Reluctantally [sic] to see selves as a major part of problems." (Exhibit 66, HSC 68) Craig said he did not recall making these comments. He did say that he believed the department was to a measure insulated from the larger politics of the HSC. He also testified that he did recognize that, as a result of their actions in May, the pediatric cardiac anaesthetists did feel as if they were being portrayed as villains.

Blanchard said that it was at this meeting that he realized that "there were serious concerns in the nursing realm as well." (Evidence, page 36,625) Blanchard explained that he knew in May that the nurses had concerns, but he believed they were largely "in the realm of compassion, of caring, of grief, you know, that sort of thing." (Evidence, page 36,625) Despite this evidence of discord, Blanchard testified that he believed at the time that it was proper to allow the program to continue at full activity.

At the end of the meeting, he distributed copies of Odim's letter to the two other department heads and to Wiseman, with instructions that they not distribute it further. Craig testified that, when he read the letter, he was disappointed and wondered if the Wiseman Committee's efforts at team building were not doomed to failure.

In his testimony, Wiseman said that the letter was disturbing in a number of respects. He was now open to Odim's recommendation of an external review.

> But an external review, because of the need for—my sense was that there was still a need for cardiac surgical expertise in the perspective of a review, which I didn't, I couldn't offer. And as you know, in terms of a genuine peer, there wasn't one in the city. (Evidence, page 40,712)

In his testimony, Postl commented that the letter disturbed him as well.

> I remember reading it and being surprised at the intensity of the comment, some of the negativity that was expressed. I think that's my memory. I was a little surprised at that. (Evidence, page 35,488)

During the autumn, Postl began reviewing the surgical results from the Pediatric Cardiac Surgery Program and concluded that the numbers were not satisfactory. He testified that he raised the issue with

Giddins. In their discussion, Giddins pointed to the small number of cases that were under review and suggested that the surgical results were consistent with the results during the period when Duncan was the surgeon. Giddins told Postl that some very difficult cases had actually gone very well. Giddins said that an improvement could be expected over time, as in Duncan's case.

This suggests that Giddins believed that Odim was progressing along a learning curve, and that events in the operating room needed to be looked at from that perspective. This was not the first time that Giddins and others had used this approach to rationalize the results that the program was exhibiting.

To repeat what has been said elsewhere in this report, it is simply not appropriate to allow patient care to be compromised while a surgeon gains experience. If it was felt results would not be as good as they ought to have been because Odim was progressing along a learning curve, greater care ought to have been taken in case selection to ensure that he did not take on cases that were beyond his level of skill and experience. That was never done.

THE CASE OF ASHTON FEAKES

ISSUES

Ashton Feakes died on November 11, 1994, after undergoing cardiac surgery on November 1, 1994.

The issues to which Ashton's case gives rise are:

- Were his parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Ashton have been referred out of the province during the summer of 1994?
- Should consideration have been given to performing a mitral valve replacement before November 10?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Ashton Feakes was born in St. Boniface General Hospital on July 15, 1993. The first child of John and Linde Feakes, Ashton was delivered by Caesarean section at 36 weeks gestation. At birth, he was diagnosed with Trisomy-21 (Down's Syndrome). At that time a heart murmur was also detected and he was diagnosed with congestive heart failure. He was treated with digoxin and a diuretic (aldactazide). On July 17 when Linde Feakes met with Giddins, he left her with the impression that Ashton needed surgery within the following six months and that the operation would likely take place in Toronto, Edmonton or Saskatoon. Ashton was discharged on August 10.

When Giddins re-examined Ashton on August 11, 1993, Ashton was in no apparent distress. His respiratory rate was 50 breaths per minute, while his heart rate was regular at 140 beats a minute. All his peripheral pulses were palpable, and the size of his liver was normal.

An echocardiogram showed:

- a right aortic arch (which means that the arch curved to the right rather than to the left)

- a complete atrioventricular canal defect
- mild atrioventricular valve regurgitation
- bilateral ventricular hypertrophy. (Both his ventricles were enlarged.)

In this defect, the tricuspid and mitral valves (the atrioventricular valves) that normally separate the heart's upper and lower chambers are not formed as individual valves. In Ashton's case, these valves were abnormal and disrupted.

An additional septal defect was identified post-operatively. Before surgery, it would have been difficult to determine if this defect was separate or a part of the atrioventricular canal defect.

His right aortic arch and his left ventricular outflow tract were unobstructed; however, he had a moderate amount of muscular obstruction of his right ventricular outflow tract as well. His pulmonary valve annulus appeared to be mildly stenotic or narrowed. His ductus arteriosus was long and narrow, but still patent.

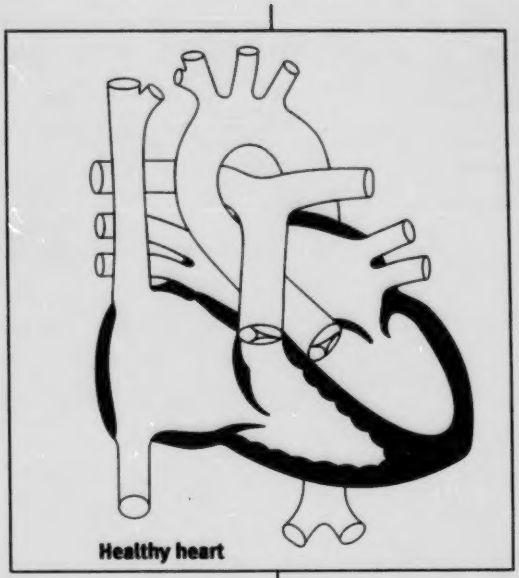
In a subsequent letter to the family doctor, Dr. Laura Hawkins, Giddins wrote that it appeared that Ashton was developing increasing muscular obstruction of the right ventricular outflow tract. This was leading to bi-directional shunting in the canal. He also indicated there was a plan for a heart catheterization. Giddins suggested that there was no reason for Ashton to continue to take digoxin, and that the dose of the diuretic could also be reduced.

A heart catheterization on September 7, 1993, led Giddins to conclude that Ashton suffered from a condition reminiscent of Tetralogy of Fallot, complicated by an atrioventricular canal defect. The catheterization also showed that Ashton had moderate atrioventricular valve regurgitation from the left ventricle to both atria.

There was a considerable degree of risk involved in repairing the combination of defects that Ashton had. For that reason, and because he felt that Ashton's condition did not make an operation urgent, Giddins decided that it would be more appropriate to undertake a surgical repair when Ashton was older and stronger. One of the reasons why a repair could be delayed was that the significant right ventricular muscular obstruction was protecting the pulmonary arteries from high pressures. Giddins said that he anticipated that Ashton's condition would evolve in one of two ways: either Ashton would develop lung congestion and difficulty breathing or the muscle obstruction would increase, causing less than normal blood flow to the lungs. Giddins decided to reassess Ashton in three months and that, in the meantime, he would not need any medication. In the end, surgery did not take place until November 1, 1994. Before then, Ashton experienced a number of serious respiratory problems.

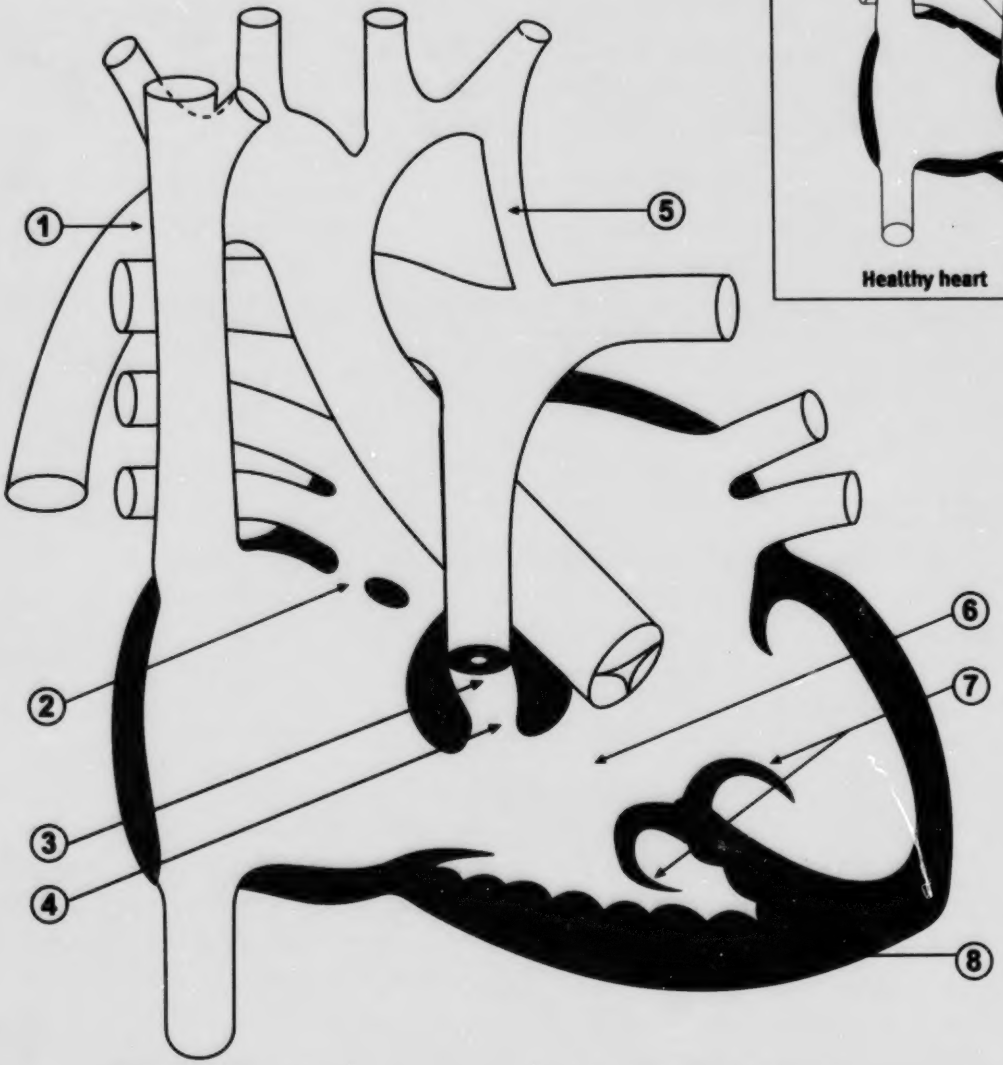
On December 10, 1993, he was taken to the HSC suffering from rapid breathing and in-drawing of the skin between his ribs and under the breastbone, a sign of his breathing difficulties. A chest X-ray showed that he had an enlarged heart, increased pulmonary flow, and possible mild pulmonary edema. The X-ray report concluded that Ashton had bilateral pneumonia. He was restarted on aldactazide for treatment of the mild congestive heart failure and was sent home at 0155 hours on December 11.

When Giddins saw Ashton on December 13, his chest was clear and his respiratory rate was 60 to 70 breaths per minute, with mild subcostal in-drawing. In his testimony, Giddins commented that, despite the interpretation of the X-ray taken when Ashton was in the HSC two days earlier, there was no evidence of any



Healthy heart

Diagram 8.5 Ashton Feakes – pre-operative heart



1 – Right aortic arch

2 – Atrial septal defect (identified post-operatively)

3 – Stenotic pulmonary valve

4 – Right ventricular outlet narrowing

5 – Patent ductus arteriosus

6 – Atrioventricular canal defect

7 – Anterior bridging leaflets

8 – Dysplastic right ventricle

infection. He also said that Ashton did not have an elevated temperature and that the X-ray showed only a slight enlargement of the heart.

Giddins concluded that Ashton was having respiratory symptoms due to the degree of left to right shunting, and should continue to be given the diuretic. He suggested a follow-up appointment in three months. In a December 14 letter to Ashton's referring doctor, Giddins wrote that his case would be taken to a CVT conference in 1994 once Odim arrived. Giddins thought that the best course of action would involve surgery in the coming year.

However, Ashton's respiratory problems were not over. On December 30, 1993, he was once again admitted to the HSC and was diagnosed with pneumonia. Ashton was treated with an antibiotic given intravenously. It would appear that his condition on December 13 was more serious than Giddins had originally thought. Ashton was discharged on January 5, 1994, on antibiotics.

THE DECISION TO OPERATE

By the spring of 1994, Giddins was giving active consideration to scheduling Ashton's heart repair. A March 30 echocardiogram showed increased right ventricular outflow tract obstruction. While the muscular right ventricular outflow tract obstruction had been giving Ashton a measure of relief from increased pulmonary blood flow, over time the obstruction itself was increasing and coming to represent a threat to adequate blood flow. Ashton continued to be given a diuretic to treat his pulmonary congestion. Giddins wrote to Hawkins that while Ashton was old enough and large enough to undergo a repair, he had no short-term concerns about his health.

On April 11, Ashton's case was presented at the CVT conference. Following this meeting, Odim arranged to discuss surgery with Ashton's parents. The Feakes testified that, based on that conversation, they expected surgery to take place in the spring of 1994.

On May 2, Ashton was admitted to the Children's Hospital with a cough, an elevated temperature and decreased oxygen saturation. After a chest X-ray showed that he had bronchopneumonia, he was given intravenous antibiotics. Ashton also had a rash on his buttocks, trunk, arms, and back. He was discharged in stable condition, still taking the diuretic, on May 17.

Odim met with Ashton's parents on May 30, 1994. In testimony, Odim was unable to explain why there had been a seven-week delay between the CVT of April 11 and the meeting with the Feakes. By the date of this meeting, the PCS program was in hiatus, as a result of the action taken by the anaesthetists. The very serious lesion that had put Ashton in the high-risk category was one that could not be repaired in Winnipeg during this period. Odim testified that he did not inform the parents of the slowdown in the Winnipeg program; nor did he suggest that they consider having the operation performed out of province.

> I guess it did not cross my mind. My sense was that was really the territory of the cardiologist and it didn't really cross my mind. They were having discussions with cardiology, cardiology refers me a patient, I see the patient in clinic. (Evidence, page 25,731)

In a letter to Ashton's doctor, Odim wrote:

> The planned definitive repair and attendant risks were discussed with the parents in detail. The natural history of medical therapy versus operative intervention was explained to the family. The higher risk in this particular subset of patients with Tetralogy of Fallot and AV canal lesions was explained to the family in detail. In view of his torrential pulmonary blood flow despite his right ventricular outflow tract obstruction and his pulmonary hypertension, which responds to oxygen therapy, I think Ashton is a candidate for definitive repair. (Exhibit 6, page FEA 5)

He also wrote, "In the interest of improving his quality of life and extending his longevity the parents are willing to take the substantial operative risk and consent to surgery." (Exhibit 6, page FEA 5)

CONSENT

In her testimony, Linde Feakes said that Odim's assessment of the risks Ashton was facing came as a surprise to her. She said from her earlier meetings with Giddins she had been left with the impression that there was 99 per cent success rate for the sort of surgery that Ashton was to undergo.

> It was just run of the mill. All of these kids, whatever, a lot of kids with Down's have heart surgery and come through no problem. Basically, when we talked to Odim, it was like he basically dropped a bomb or something.
>
> I don't know, we came in there with—okay, we are going to meet the surgeon, no problem, and we left like totally in tears and everything. He told us that the repair Ashton had to have done, in the worldwide centres, like in the world renown centres or something like that, they had an 80 percent success rate with that surgery. And in Winnipeg in the last 10 years, they hadn't saved one with that surgeon—I mean with that surgery.
>
> We didn't know why it was so—why all of a sudden the big change. His answer was because it was rare for a kid to have all of those defects in the same heart, because there is kids that have the different parts and those are easier to fix, but Ashton had so many things wrong with his heart.
>
> And he told us he was from Boston. He just came from Boston, and that was one of the major world centres that he named. So we were assuming that this would mean that he would have an 80 percent survival rate also, if Boston did.
>
> And we asked him how many of these surgeries [he] had done . He told us he did one under supervision, on his own, and he had assisted with some, I don't know how many, and he did all of these other parts individually, but it's rare to find them all together. So, that's why he hadn't done it often, all together in one kid. (Evidence, pages 2,891–2,892)

Linde Feakes also testified that Odim said the operation should be done right away. He also suggested that it should have been done by that time. John Feakes said that at first he thought Ashton should be sent out of province, but concluded that because Odim was from Boston, it would be appropriate to have him treated in Winnipeg.

The Feakes expected to hear back from Odim by the end of the first week in June. However, no date was set during this period. Linde Feakes indicated that the family had been expecting that surgery would take place during the summer, before Ashton's July 15 birthday. She said that the reason given to them about delay was that there was a backlog, not that the program had slowed down. She said that during the summer, no one raised the possibility of sending Ashton out of province, even though other children were being referred to other centres during this time.

Following a July 6 VCHC visit, Giddins wrote to Dr. Hawkins that it was likely that a date would be arranged for September or October. However, he said that this could not be finalized until the end of August. He also wrote that the family understood that there would be a delay. In his testimony, Giddins was asked on what basis he had made the prediction that it would be possible to undertake the surgery in September or October. He replied:

> My belief that the issues that were resulting in the hiatus at the time were going to be and, in fact, were being addressed, and the program was developing appropriately. (Evidence, page 4,108)

When Giddins was asked if he had told the family of the slowdown in the program, he said he did not believe he had, since "It had no pertinence to Ashton's surgical care in the future." (Evidence, page 4,109) Giddins did acknowledge that the operation was deferred until the re-establishment of the program and that he had not informed the parents of this fact.

Linde Feakes testified that following the July 6 meeting with Giddins, the family again thought that surgery would take place soon. When she pointed out that Odim thought the operation should have taken place immediately, she said that Giddins told her that there was no danger in delay. In his testimony, Dr. Walter Duncan said that Ashton was still an acceptable candidate for surgery in late October, despite the delay.

It was only after the program resumed full operation in September 1994 that a final decision was made to perform surgery in Winnipeg. The initial decision was to schedule the operation for October 18. It is apparent that if it had not been for the program slowdown, Ashton would have undergone surgery in the late spring or summer of 1994.

It should be noted that this was an extremely high-risk procedure. Giddins testified that he would describe this repair as relatively high-risk, having a risk factor of 25 per cent. While Cornel and Dr. Walter Duncan agreed that the surgical approach that Odim employed was appropriate, they noted in their report that:

> this is one of the more difficult types of repair to do well. Statistics are not favourable. Estimated Canadian risk for surgery in this condition may be as high as 10–20%. (Exhibit 354, page 13)

Soder gave this description of difficulties involved in this surgery.

> We often refer to mitral valve surgery and AV canal surgery as an art. It is like sewing wet tissue paper is how our surgeons describe it. It takes a degree of creativity and artistry that I don't understand to make those filmy leaflets somehow line up and function in a reasonable fashion, because the canal is such a gross malformation of normal anatomy, and this isn't sewing firm tissues together in a sort of predictable mechanistic fashion. So it involves the highest level of skill, and in my opinion a great deal of intuition to get it right. (Evidence, pages 44,195–44,196)

As difficult as it sounds, this approach is preferable to putting in a prosthetic valve. Such valves require that the child take medication to ensure that there is no clotting around the valve. Furthermore, as the child grows, there must be further operations to replace the valve as the heart becomes bigger.

It is reasonable to ask if, in undertaking this operation, the team was not once more—to use the words of the Wiseman Committee interim report—taking on a case 'of an order of complexity that exceeded the program maturity.'

The operation was set for October 18, but was postponed when Ashton was found to have petechiae. These are minute reddish or purplish spots caused by hemorrhaging in the skin or mucous membrane. In some patients, the presence of petechiae means that there are not enough platelets. In other patients, petechiae are associated with a platelet dysfunction. (Platelets normally assist in blood clotting.) On October 5, Dr. Rachelle Yanofsky, an HSC hematologist, examined Ashton and concluded he had very mild petechiae and mild polycythemia (an increase in the total number of red cells of the blood). She recommended that Ashton not be treated with aspirin or antihistamines pre-operatively.

The results of an October 17 heart catheterization were essentially unchanged from the previous catheterization, except that the muscle bundles causing the right ventricular outflow tract obstruction were noted to be increasing in size and significance. The consulting witnesses agreed that Ashton had been diagnosed correctly. His parents gave formal consent for his operation.

PRE-OPERATIVE STATUS

Ashton was scheduled for surgery on November 1 and was admitted on Monday October 31, 1994. On admission to the HSC, Ashton was breathing rapidly, with his ribs clearly showing each time he took a breath. However, his chest was clear and in his testimony, Giddins said he believed that Ashton was fit for surgery. The report from the anaesthesia consultation indicated that Ashton was seen to be high risk, but that a decision had been made to proceed with the operation.

THE OPERATION—NOVEMBER I

On Tuesday November 1, Ashton underwent:

- a single-patch repair of the complete atrioventricular canal defect;
- division of the anterior bridging leaflets, with re-suspension, of the mitral and tricuspid components, to the pericardial patch (or refashioning of the existing components of the mitral and tricuspid valves, using material from the pericardium);
- Reed annuloplasty of the mitral valve (or repair of the opening of the mitral valve);
- closure of the mitral valve cleft;
- pulmonary valvotomy (or enlargement of the pulmonary valve opening);
- excision of the extensive parietal muscle bundles within the right ventricle; and
- ligation of the patent ductus arteriosus.

The operating team is set out in the accompanying chart.

TABLE 8.5: Persons involved in the operation on Ashton Feakes, November 1, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	B.J. Hancock
Anaesthetists	H. Reimer, J. Doer (resident)
Scrub nurses	C. Youngson, C. McGilton
Circulating nurses	B. Zulak, C. Weber, K. Cox
Perfusionists	M. Maas, D. Smith

The myocardial protection used was moderate hypothermia and intermittent cold blood cardioplegia.

TABLE 8.6: Length of phases of the operation on Ashton Feakes, November 1, 1994

Phase of the operation	*Time taken*
Induction	1 hour 47 minutes
Bypass	3 hours 21 minutes
Aortic cross-clamp	1 hour 57 minutes
Total surgical time	6 hours 20 minutes
Total operating-room time	8 hours 22 minutes

Odim testified that in his opinion, the repair in Ashton's case went very well. The other participants in the operation raised no issues about this procedure. However, Soder said that a procedure of this length would give him some anxiety.

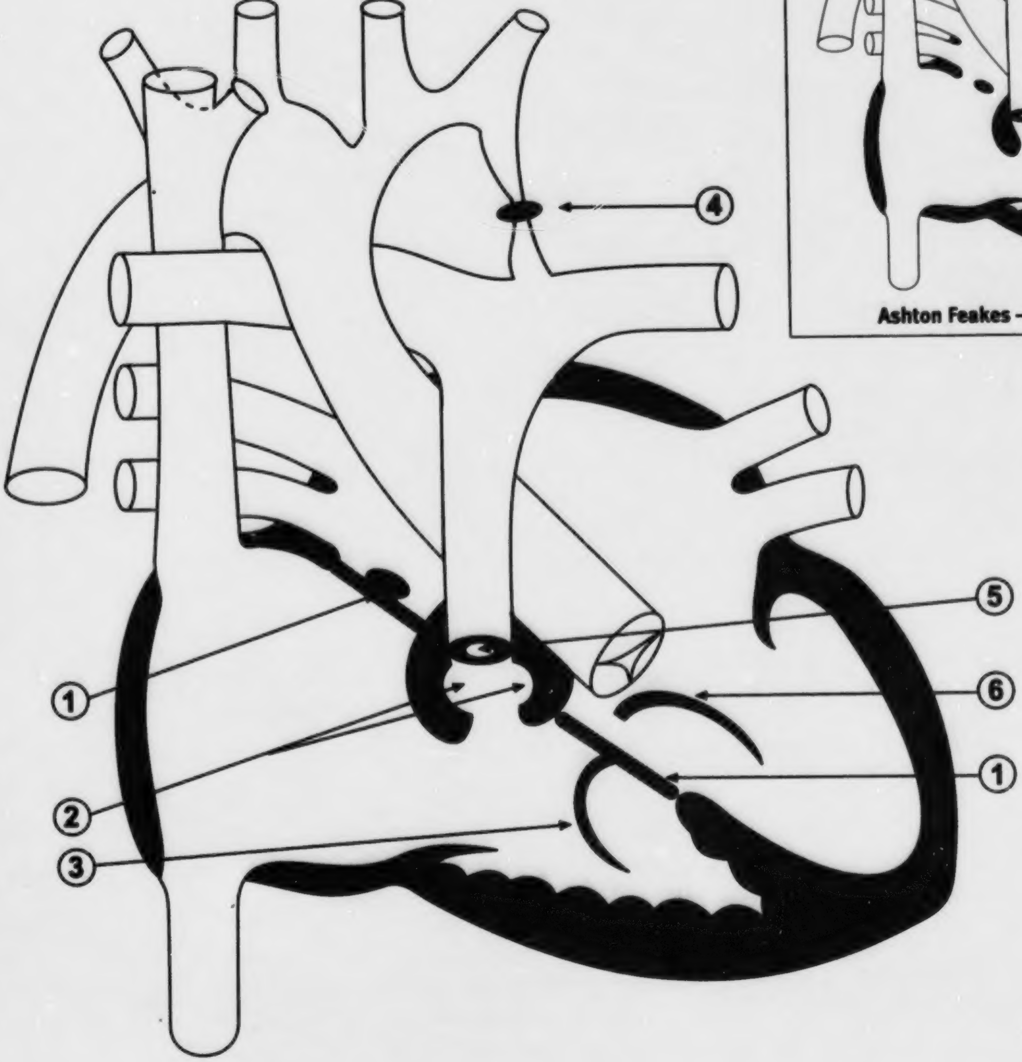
During surgery Ashton experienced problems with heart block that continued during his post-operative treatment. He had third-degree heart block during the closure of his chest, which required cardiac pacing.

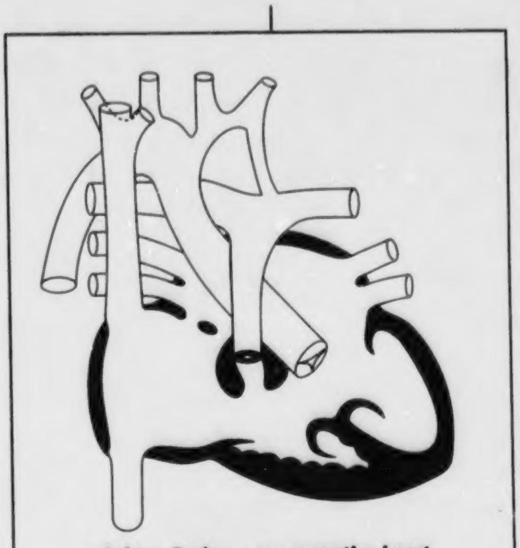
Aside from the fact that withdrawal from bypass required substantial doses of inotropes, Cornel concluded that the "surgery appears to have been otherwise uneventful. Intraoperative pressure recordings were consistent with a satisfactory repair. The pulmonary artery pressure was elevated but the left atrial pressure and central venous pressure were within expected range." (Exhibit 353, page 59) In their joint report, Cornel and Duncan noted that the patches appeared to be intact and appropriately placed. In his testimony, Dr. Walter Duncan said, "I think it was well done. This is a difficult repair, I think his patches were intact, his valves looked okay, his pressures were perfect." (Evidence, page 41,451)

POST-OPERATIVE COURSE

The operation that Ashton underwent placed a tremendous strain on his system. It was not expected that he would return to the PICU in anything other than critical condition. However, the expectation was that after 24 hours, he would begin to improve. Initially, Ashton followed this course. However, on November 5, four days after surgery, his condition began to deteriorate. From that point on, he never recovered.

Diagram 8.6 Ashton Feakes – post-operative heart





Ashton Feakes – pre-operative heart

1 – Single pericardial patch of atrioventricular canal defect

2 – Partial excision of the extensive parietal muscle bundles within the right ventricle

3 – Resuspended tricuspid valve

4 – Ligated ductus arteriosus

5 – Pulmonary valvotomy (or enlargement of the pulmonary valve opening)

6 – Resuspended mitral valve (with subsequent dehiscence)

Recurring issues during his post-operative care were an increase in regurgitation through his mitral valve, problems with his heart rhythm and concerns that he may have been suffering from a lung infection.

On November 10, it was discovered that his reconstructed mitral valve was no longer functioning. In light of this finding, one of the central debates over his post-operative care was at what point should the team caring for him have considered performing a valve replacement. One of the signs of mitral valve failure is regurgitation through the mitral valve. However, regurgitation is common following surgery of this nature—the challenge is to determine if the level of regurgitation is excessive and indicates a need to re-operate.

Doyle admitted Ashton to the PICU following his operation. At the time, she noted that he had low blood sugar, low blood pressure, metabolic acidosis, an elevated temperature and a decreased number of platelets in his blood. Except for his left upper lung, he had good air entry to his lungs. She concluded that Ashton's heart was unstable, with poor contractility and residual regurgitation through an atrioventricular valve, and with low blood pressure. Doyle testified that this was not unexpected, given Ashton's condition before surgery. Ashton was treated for the conditions Doyle had identified and his condition stabilized. However, Doyle testified that as efforts were made to reduce those treatments, Ashton's condition deteriorated.

An echocardiogram performed immediately after surgery showed abnormalities in the function of the left ventricle and mild tricuspid regurgitation. The possibility of mitral valve stenosis was also questioned. However, there was no mitral valve regurgitation. Giddins testified:

> I was perhaps surprised by that because that was surprisingly good, I would have expected some leak. (Evidence, page 4,342)

Based on the results of that echocardiogram, Giddins said he thought that the operation had gone very well.

For the first eight hours following surgery, Ashton's left and right atrial pressures were both elevated, but were approximately the same. After eight hours, however, the left atrial pressure increased and remained higher than the right atrial pressure. According to Cornel, this was a possible indication of dysfunction on the left side of the heart and, in particular, of a problem with the atrioventricular valve repair (that is, the mitral valve).

Throughout his stay in the PICU, Ashton experienced heart block. Odim said that Ashton had sinus (or normal) rhythm when he came off bypass, so he thought the block was not a technical issue. Odim said he thought it might have had a metabolic source or might have been related to swelling in the tissues of the heart.

On November 2, Ashton's metabolic acidosis improved, but he still needed pacing. Giddins wrote that Ashton had complete atrioventricular heart block with a paced ventricular rate of approximately 120–130 beats per minute. He said there was "very little 'coordinated atrial kick' but when pacer placed in backup mode, every 2nd vent [ventricular] impulse preceded by atrial kick therefore this seems optimal for now. Other aspects of of [sic] status all look satisfactory." (Exhibit 6, page FEA 80)

What Giddins was describing was a way of pacing the heart by stimulating only the bottom part of the heart – the ventricle (or "paced ventricular rate"). When Ashton's heart was paced at a rate of 120–130 beats per minute, there was no spontaneous activity from the atrial or top part of his heart. However, when the pacer was put in the backup mode (and not actively pacing), then Ashton's heart would produce a small beat from the top of the heart, in the form of an 'atrial kick'. This 'kick' represents a small amount of blood that is ejected and helps with the overall output of blood from the heart. Giddins believed that this situation was the best for the time being.

In his report, Cornel wrote, "The rhythm management was questionable. AV sequential rhythm would probably have produced a significant improvement in cardiac output. AV sequential rhythm might have been achieved by administering digoxin combined with AV pacing at a faster rate than the atrial rate." (Exhibit 353, pages 61–62)

Cornel was suggesting that a better way of managing Ashton would have been to use AV sequential pacing, in which the atrium was stimulated electrically, followed by electrical stimulation of the ventricle. Cornel indicated that the technique would involve two components. First, Ashton would have to be given digoxin, a drug that can be used to slow electrical conduction between the atrium and the ventricle. Second, the pacemaker would have to be set at a rate faster than the rate at which Ashton's heart was attempting to beat on its own. By doing these two things, Ashton's heart would be able to contract in a way that most closely resembled normal, with the result that Ashton would have had improved output of blood flow from his heart.

On November 3, Ashton had an elevated temperature and was treated with diuretics to address his low urine output. While Ashton still had heart block, Giddins said, he was satisfied with his heart rhythm.

Increase in mitral regurgitation

On November 4, Ashton's chest was clear and the process of weaning Ashton from mechanical ventilation was started. Giddins testified that he was not concerned by Ashton's continued heart block. He said it was his practice to wait at least a week to determine if a child then needed a permanent pacemaker.

Ashton was still being given inotropes. An echocardiogram showed that he had good ventricular function, right atrial enlargement, right ventricular hypertrophy, mild mitral stenosis, moderate mitral regurgitation and mild right ventricular output obstruction. Giddins said these results indicated that Ashton's condition was continuing to improve.

The consulting witnesses to this Inquest raised questions about the mitral valve regurgitation. According to Cornel, the leakage could have been due to the components of the valve becoming pulled apart or because the valve was becoming detached from the suture line. Cornel said the regurgitation likely became significant following the increase in the left atrial pressure. He thought it would have been appropriate for the post-operative care team to have considered whether or not mitral valve replacement was required at that time.

Cornel acknowledged that such a replacement was a difficult procedure. However, he said:

> ... the outcome of doing nothing with a severely regurgitant valve, where the heart is not managing to cope with the regurgitation, the outcome of that is terrible. (Evidence, page 44,894)

Soder testified:

> In general, our approach has been to let the general clinical condition of the patient guide us. If the patient appears to be on the mend, we tolerate up to moderate degrees of mitral valve regurgitation

> or tricuspid regurgitation. If the patient appears to be deteriorating and getting into trouble, then we re-investigate and possibly re-operate. (Evidence, pages 44,183–44,184)

Odim was asked if there was any consideration of a re-operation on November 4. He said there was nothing to suggest that the repair had broken down.

> Furthermore, we—the child was being ventricularly paced and we know that ventricular pacing will make mitral regurg worse because what happens is you are pacing the ventricle at a rate that is not congruous with the atrial, the atrial rate in the patient, and many a times, this impulse comes down through the tissue and it bombards this area and you get what is called a V-wave, so he was being ventricularly paced which we know exacerbates mitral regurg and there were issues of this being a functional problem because of the loading conditions on the pump. (Evidence, page 25,758)

Thus, as well as ventricular pacing producing less than optimal cardiac output, there was a possible second problem in the effect on the mitral valve. With artificial pacing of the ventricle only, there is no co-ordination with any spontaneous activity from the heart's normal atrial pacemaker. Then, if the atrial pacemaker does cause the atrium to contract, the result is what is known as a 'V-wave' that exacerbates mitral regurgitation.

A chest X-ray on November 4 showed slightly increased but unidentified spots in the left upper lobe and a new right pleural effusion. (This is the term for the fluid that fills the space between the chest wall and the lung. Pleural effusions can occur as a result of congestive heart failure.)

On November 5, there was no improvement. Giddins said this lack of progress actually indicated a significant change for the worse, since he had expected that Ashton would have been improving by this time.

A chest X-ray taken early in the morning of November 6 showed pulmonary edema, with increased pleural effusions on both sides of the chest. Ashton's platelets began to drop in number and remained low despite transfusions. Tests were done to see if he had a viral infection, which could have been associated with a decline in his oxygen saturation. However, Giddins testified, the results of those tests took a while to come back and little could be done about such viruses in any event. It does not appear that any requests were made to have the performance of the tests expedited. From this point on, the post-operative care team checked for a variety of infections, although none were identified during this period.

Over the next 24 hours, Ashton's oxygen saturation decreased, and he required more oxygen and manual ventilation. He retained fluid and his weight consequently increased, for which he was treated with diuretics. A chest X-ray showed that he had a collapse of his right upper lobe and pulmonary edema. An echocardiogram showed that the mitral valve now had moderately severe regurgitation. The tricuspid valve also showed an increased volume of regurgitation.

November 7—the mitral regurgitation worsens

By November 7, Ashton was again given doses of muscle relaxants to completely weaken his muscles. The aim of this treatment was to reduce oxygen use by the muscles, thereby reducing his heart's workload.

An echocardiogram showed that Ashton had moderate to severe left atrioventricular (mitral) valve regurgitation. Giddins said this was the first clear evidence that the valve was failing. Soder said he would then have called his team together to discuss the possibility of repair of the mitral valve. Soder would also have liked to have seen another heart catheterization done at that time.

However, Giddins said, there was no cause for a re-operation at that point.

> Knowing, though, that in these cases moderate to severe valve regurgitation isn't an impediment in some cases to them leaving the ICU, we maintain a philosophy that, if at all possible, we should improve everything else that we can do in the intensive care unit before thinking of something like more surgery to address a failing valve.
>
> *Q:* Would this have been the first day that the thought of a redo, or going back into surgery occurred to you?
>
> *A:* Before going back into surgery, we would want pretty solid documentation that there was no alternative. (Evidence, pages 4,366–4,367)

Giddins also said he did not believe that Ashton was in any condition for surgery on November 7. Given the fact that Ashton was becoming more edematous, Giddins decided not to perform a heart catheterization until his condition improved. Catheterization itself, he felt, would put considerable stress on a child in Ashton's condition. The dilemma that Giddins faced was whether Ashton's problems were the result of a viral infection or from a failed mitral valve repair. Because a re-operation entailed significant risk, Giddins wanted to rule out all other possibilities, before considering valve replacement.

November 8—a small improvement

Giddins thought that Ashton's condition was improving on November 8. His oxygen saturation was increasing, his fluid overload was resolving and his platelet count had not decreased further. However, he was still in heart block and still needed the pacemaker.

The same day, a hematologist was consulted to look at persistent thrombocytopenia (or low numbers of platelets in the blood). The hematologist suggested treating the condition with platelet transfusions until the surgical site healed. The opinion of the hematologist was that the number of platelets was low because they were being used to form clots around the wounds.

November 9 – a turn for the worse

Ashton's condition started to deteriorate once more on November 9. His oxygen saturation fell when staff attempted to keep his lungs clear of secretions, through what is termed chest physiotherapy. His platelet count, however, was stable. Giddins thought that Ashton's condition was not as bad as on November 7 but not as good as on November 8.

November 10—the opportunity for mitral valve replacement passes

On November 10, Ashton suffered a hemorrhage from his lungs that left his system so weakened that it was no longer possible to consider valve replacement. It was also on November 10 that the results of a heart catheterization showed that such a replacement was necessary.

At 0445 hours that day, Ashton's oxygen saturation decreased. Pink frothy sputum was suctioned from his lungs. This is often a sign of pulmonary edema and its increased presence was confirmed on a chest X-ray. Over the course of the day, subsequent chest X-rays also showed a large left pleural effusion, the fact that both lungs appeared more dense in patches, and there was the possibility of a pneumothorax on both sides of Ashton's chest. (A pneumothorax is the abnormal presence of air in the space between the lung and the chest wall.) Ashton was not responding to aggressive treatment.

By this point, he had developed what Soder called frank pulmonary edema.

> By frank pulmonary edema we mean that the pulmonary edema fluid is now actually bubbling up through the endotracheal tube and is externally visible, as opposed to just X-ray findings of pulmonary edema. (Evidence, page 44,191)

The pink froth was an indication that Ashton was hemorrhaging into his lungs. The development of pulmonary hemorrhage was a turning point in his post-operative deterioration.

An echocardiogram showed a small VSD leak, two forceful leaks (or jets) from the left ventricle to the right ventricle and severe mitral regurgitation, with shunts from the left ventricle to the right atrium.

Giddins and Soni performed a cardiac catheterization in the PICU, using a special portable X-ray machine. The procedure was complicated by Ashton developing a marked slowing of his heart rate and a drop in his blood pressure that required chest compressions for about five minutes. The catheterization showed severe mitral valve regurgitation, passive pulmonary hypertension and severe left ventricular function. Giddins wrote:

> It is clear to Drs. Ward, Odim and I that no [underlining in original] further specific operative intervention would be tolerated; even if it were, prosthetic mitral valve management is extremely difficult (both short and long term) @ this age + size. ...prognosis nearly hopeless, and I would hope comfort is maintained as a priority. Family informed of above. (Exhibit 6, page FEA 101)

Swartz, who was the intensivist, also agreed that, following his lung hemorrhage, Ashton would not tolerate being placed on bypass, which would be required if his mitral valve was to be replaced.

Soder testified that from his perspective, the pulmonary hemorrhage was the terminal event in Ashton's case.

> In my opinion the kind of the last chance to really do surgery was somewhere before he developed pulmonary hemorrhage on November 10. I think reoperating on his mitral valve up until that point still had a significant chance of success. Once you are into the situation of frank pulmonary hemorrhage, the likelihood of surviving surgery becomes very, very minimal. (Evidence, pages 44,193–44,194)

Dr. J. Embree of Infectious Diseases examined Ashton on November 10 and concluded that she did not believe an infection was playing a significant role in Ashton's problems. He had tested positive for coagulase negative staphylococci. However, she said that these bacteria could not have caused the problems that Ashton was experiencing.

Her notes indicated that she wondered if it was too early in Ashton's case to see signs of cytomegalovirus (CMV). This was a virus that was more common in adults than in children. However, Embree said that it was a virus present in all humans at all ages, but that the body's natural immune system is usually able to control it. In infants and immune-compromised persons, however, it has serious, permanent consequences. CMV infections can cause an opportunistic, severe pneumonia that may be life-threatening. She said that at the time of Ashton's surgery, there was no effective treatment for CMV infection.

After seeing Ashton, Embree recommended a fine-tuning of his antibiotic treatment, ongoing surveillance for further infections, and that samples be sent to be tested for various viruses (including CMV) and bacteria. Unfortunately, due to an error in the transmission of this request, no test for CMV was performed.

Linde Feakes testified that on November 10, Giddins told the family it was unlikely that Ashton would survive the night. John Feakes testified that it was made clear to them that it was not possible to repair or replace the mitral valve, given Ashton's weakened condition.

Throughout the evening, Ashton's condition continued to deteriorate. At 2400 hours Swartz wrote that Ashton was being given large doses of inotropes and maximum artificial ventilation, with no significant improvement.

November 11

On Friday, November 11, Ashton's condition continued to deteriorate. He had significant elevation of his pulmonary arterial pressure as a result of the mitral valve regurgitation. He was suffering from a progressive lack of oxygen in his blood and his kidneys had stopped making urine. Artificial kidney dialysis was successfully carried out that afternoon.

Linde Feakes testified that on that morning Odim informed her that it was still possible for Ashton to pull through. That statement proved to be more hopeful than accurate. Ashton was given comfort care to reduce his pain and died at 2027 hours on November 11, in the presence of his parents.

POST-MORTEM FINDINGS

The debate over whether Ashton's deterioration was driven primarily by a failing mitral valve or by an infection appeared to have been firmly settled in the autopsy report.

The autopsy was performed on November 13, 1994, by Dr. Joseph de Nanassy, and was restricted to an examination of the heart and lungs. While a preliminary report was issued on December 13, 1994, the final report was not completed until February 20, 1995. In the preliminary report, there was no mention of a finding of evidence of a viral infection in the lungs.

In the final report, de Nanassy determined there was extensive recent hemorrhage in both lungs and that there was pulmonary necrosis related to cytomegalovirus infection (CMV). He also noted marked bilateral myocardial hypertrophy. He concluded the most likely cause of death was the pulmonary hemorrhage. The implication from this was that the CMV attacked tissue in Ashton's lungs, leading to pulmonary necrosis. The weakening generated by this necrosis in turn could have led to the hemorrhaging and to Ashton's death.

As noted above, CMV is a very serious viral threat to children in Ashton's condition. While Embree had raised it as a possibility, no one involved in Ashton's treatment had thought it likely that he suffered from such an infection. Giddins testified that he was surprised at the results of the autopsy.

Consulting witnesses to this Inquest have come to a different conclusion about the cause of Ashton's death. Soder, Duncan, Cornel and Taylor each concluded that the problem lay with the dysfunctional mitral valve and not with CMV. Taylor testified, in fact, that he did not believe that Ashton had a CMV infection.

When Cornel examined the heart, he said that the degree of disruption of the AV valve was very severe.

> The leaflet was almost completely detached. So that the degree of competence of the valve would have been minimal. It is an extremely severe lesion. (Evidence, pages 44,891–44,892)

When asked how this could happen, Cornel testified that the suture line bears the entire stress of left ventricular contraction and pressure.

> If there is a tiny defect anywhere in that suture line, there is going to be added stress at that point and it may start to tear. Once a tear has begun, it becomes a progressive weakness, like tearing a stamp along the perforation. So the tear may very well be progressive. It is one of the reasons I don't do this type of repair anymore. There is a higher incidence of leaflet dehiscence in the one patch repair than some other types of repair. (Evidence, page 44,892)

Dehiscence means the coming apart of the surgical incision or suture line. It was Cornel's view that the leaflet tissue remaining on the mitral valve that had been sutured to the patch had come away from the suture line. When asked about his positive assessment of the surgery and the mitral valve regurgitation, Duncan testified:

> It doesn't matter which surgeon where does an AV septal defect repair, the left-sided inlet valve will always leak after surgery, some more, some less. It depends how much tissue you have to work with.
>
> This valve was behaving satisfactorily at the completion of the surgery, but I presume either the sutures pulled out or maybe became infected and pulled through, I don't know. But for whatever reason, the valve began to perform much worse in a relatively short period of time and just became progressively more so. (Evidence, pages 41,452–41,453)

De Nanassy disagreed that there was valve dehiscence, because, he said, there was no valve tissue to dehisce in the first place. Taylor, however, said that if that had been the case, Ashton would have been in trouble immediately after surgery.

> So in my opinion the leaflet valve tissue was attached to that patch. The suture line was there, although part of those sutures are for the other side, the tricuspid valve. And the leaflet pulled away from the patch, apart from the suture line, dehisced over the course of the clinical events leading up to the child's death. (Evidence, page 43,260)

Odim said that he was surprised to read Taylor's conclusion about dehiscence.

> Certainly when I saw this I was a little bit surprised because certainly when Ashton was alive we were looking for evidence of this on his studies, echos and cath. So I was a little surprised by that finding.
>
> I was also surprised because I think I recall looking at the specimen and I certainly don't remember picking this up and we may have looked at it as a group, I don't remember whether this was done in the setting of the M & M round. (Evidence, pages 25,771–25,772)

Taylor said there were three potential explanations for the suture line coming apart. They can be summarized as follows:

- There could have been an infection that undermined the repair. If the wound had become infected, the suture line would have 'softened', allowing the sutures to loosen and pull away.
- Technique: the sutures needed to be placed deep enough to have a sufficient grasp on the tissue being sutured. If not, they could have easily pulled out.
- Ashton could have had an inherent problem in the mitral valve tissue that prevented it from holding the suture.

As was mentioned, Taylor disagreed with the conclusion that the child had a CMV infection that caused the necrosis. He noted that the child had been checked for infection numerous times before death and no one had noted any infection. He said that CMV grows fairly easily and therefore would have been easily detectable. Embree confirmed this. It should be noted that de Nanassy did not actually test for the presence of CMV, but reached his conclusion based on observation.

Tests conducted by Taylor on sections of the lung were negative for the presence of CMV. He did feel that Ashton had bronchitis and pneumonia (both bacterial, rather than viral, infections) and that these bacterial infections led to the necrosis. He pointed to the fact that samples of endotracheal secretions that were taken from Ashton on November 7 tested positive for bacterial infection. It is not known when the results of these laboratory tests of November 7 were available to the team caring for Ashton.

Taylor thought that the mitral valve regurgitation could have led to a backup of fluid in the lungs that would have led to an infection in the lungs. This would then have led to the pulmonary hemorrhaging that eventually led to Ashton's death.

Taylor also thought that the infection could have moved along the suture line, causing the valve to dehisce. This would also have led to regurgitation of the mitral valve and the resultant backup of fluid in the lungs, leading to pulmonary hemorrhaging. As a result, Taylor concluded that the two key factors in Ashton's death were the mitral valve regurgitation and the necrotizing pneumonia.

In his report, Taylor wrote:

> The clinical history of the post-operative period indicates progressive development of mitral regurgitation. Initial echocardiogram showed no regurgitation while the last echocardiograms showed moderate to severe regurgitation. On the last day of this child's life it was clinically appreciated that he needed mitral valve replacement. My examination of the post-mortem heart specimen showed the anteromedial leaflet of the mitral valve to be separated from the suture line to which it was suspended from the atrial ventricular septal defect patch. This was also reported on the initial autopsy examination of the heart. Progressive dehiscence of this leaflet from the patch would cause the clinical findings recorded in the postoperative days. The finding of massive pulmonary haemorrhage is in keeping with fulminant mitral valve regurgitation. (Exhibit 336, page 10.1)

FINDINGS

As noted at the outset, the following issues arise in this case:

- Were Ashton's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Ashton have been referred out of the province during the summer of 1994?
- Should consideration have been given to performing a mitral valve replacement before November 10?
- What was the cause of death and was it preventable?

Were Ashton's parents provided with sufficient information to allow them to give informed consent to the procedure?

■ Finding

As in the other cases dealt with by this Inquest, the evidence suggests that the parents did not receive sufficient information to give informed consent. They were never informed about the state of the team during the summer months while they were waiting for the operation to be performed. While Odim and Giddins were probably accurate in their assessment of the degree of risk that the operation presented, the evidence would suggest that they did not seem to have factored into their thinking the relative inexperience of the surgeon and of the team in dealing with this type of surgery. This information is something that would probably have been a factor in the thinking and granting of consent by any reasonable person, and should have been provided to the Feakes. This evidence tends to suggest that Ashton's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Should Ashton have been referred out of the province during the summer of 1994?

■ Findings

Given the seriousness of Ashton's condition, it would have been appropriate for the VCHC to have referred Ashton out of province for surgery in the summer of 1994. It was clear that Ashton was not an appropriate patient for the surgical team to undertake care of, during the summer of 1994, when the program was in hiatus and performing only low-risk procedures.

During the summer months, the review team was considering the question of whether or not to allow the program to proceed to high-risk cases. At that time, Giddins, in consultation with the Wiseman Committee, made the decision to defer high-risk cases until the program could do them. No consideration was given to transferring such patients unless the parents demanded that the child be transferred or unless the patient could not wait for surgery.

The Feakes were not given the option of considering a referral to another centre. They should have been. More importantly, however, was the fact that Ashton could not have benefited from waiting additional time for his surgery. There is evidence that Odim thought the operation should have been done sooner, rather than later. While the program waited for the hiatus to end, Ashton's condition was becoming worse. His muscle bundles, for example, became more and more problematic as time passed.

The evidence suggests that the team and its surgeon were not in a position, even in November, to be able to provide the best possible care for this child. While the operation was judged a success, it was a very high-risk process. It may be that the valve dehisced as a result of a problem with surgical technique, although this is only a possibility. However, it would have been appropriate for the team to have referred this child out of province, even after the PCS program had gone back to full service.

Should consideration have been given to performing a mitral valve replacement before November 10?

- Findings

The treatment team came to the conclusion on November 10 that the surgical repair had failed and that the mitral valve needed to be replaced. However, by that time, Ashton had deteriorated to such a condition that it was not possible to consider another surgical procedure.

There is evidence to suggest that the team had sufficient information before November 10 to enable it to consider performing a mitral valve replacement. Cornel was of that view. He thought the echocardiogram on November 4 showed that the regurgitation was at the point of indicating a valve repair failure. Soder's view was the same. He said that so long as the patient was improving, regurgitation was tolerated, but the evidence suggests that Ashton did not improve to any degree after November 4. Giddins felt that Ashton's failure to improve on November 5 was actually a sign that he was getting worse.

By November 7, Ashton was showing evidence of an inability to tolerate another surgical procedure. That should have caused the team to consider a valve replacement if Ashton rallied, which he did on November 8. However, despite interpreting that as a sign of overall improvement—which seems more like wishful thinking, in hindsight—no steps were taken to replace Ashton's mitral valve. He quickly deteriorated thereafter.

What was the cause of death and was it preventable?

- Findings

It seems clear that Ashton died from pulmonary hemorrhage. The question is: what caused the hemorrhage? The consulting witnesses believe that the dehiscence of the mitral valve repair led to the mitral valve regurgitation that ultimately led to Ashton's lungs becoming congested and hemorrhaging. No firm conclusion can be reached as to what caused this dehiscence.

The evidence also suggests that with a different approach to post-operative care, a decision would have been made earlier on to repair the dehisced mitral valve, although this would have been a high-risk venture.

Both the dehiscence and the failure to attempt to repair the mitral valve do lead to one very significant conclusion: this death could have been prevented if the case had been referred to a larger medical centre in the summer of 1994, rather than being deferred until November 1994.

EARLY WINTER

On November 2, Postl, partly at Blanchard's prompting, met with Odim over lunch. At that meeting, Odim told Postl that he felt that a number of team members had not given him a fair chance. He also indicated that there was a poor turnout for M & M Rounds. Finally, Odim restated his belief that fewer anaesthetists should provide anaesthetic care to pediatric cardiac surgery patients. After this meeting, Postl attempted to attend a pediatric cardiac M & M Round, only to discover that it had been cancelled.

At some point in late autumn or early winter, Postl received a phone call from Ward, who said that he had met McNeill by chance at a public skating rink. Postl testified that Ward told him about his conversation with McNeill. She had said to Ward that the only problem with the Pediatric Cardiac Surgery Program was Odim. If he was removed from the program, then it would be fine. Ward told Postl that this was evidence that the anaesthetists were not giving Odim a chance. Postl spoke to Craig about the encounter, who in turn, passed the information on to McNeill. In her testimony, McNeill gave this account of her meeting with Ward.

> So he and I skated together for a little while; and during that time I expressed my concerns with some of the recent events in the operating room, that perhaps some of our concerns that we had had earlier in the spring were recurring. I guess I was partially informing, partially ventilating, and partially asking what he thought of what had occurred, because he knew some of the patients involved.
>
> At the time, I didn't really think much of the conversation, it was shop-talk type of a thing. He was one of the cardiologists in the program, and I thought it was a reasonable thing to talk to him about events that were occurring in the program. (Evidence, page 13,530)

McNeill testified that Craig told her he thought her comments would serve to undermine the program. McNeill arranged to meet with Postl. She testified that she:

> ... explained to him, you know, that I really hadn't meant to be malicious or had no intent to undermine the program, and it was really, I thought, a relatively innocent conversation between people that were involved in the same work. (Evidence, page 13,532)

Postl said that he did not view the encounter as a major issue, but recommended that she not be indiscreet in public places.

Postl testified that as November progressed, he became troubled that the numbers of concerns about the program were increasing. Also, he said, people seemed to be, in his words, simply handing off their concerns when they reported them to someone else. The problem appeared to be, however, that those to whom the concerns were being reported were not resolving the issue.

On November 7, Craig wrote to Blanchard, stating that he had read Odim's letter and saw it as a warning. He recommended that there be an external review of the program (Exhibit 19, Document 265).

Odim testified that some time after he sent his letter to Blanchard, Craig spoke to him about Odim's concerns with anaesthesia. Odim recalled that Craig told him that he would ask Reimer if he was prepared to do the majority of Odim's cases. Odim said that Craig also told him about the possibility of having Dr. Heather Tulloch work with Odim. Tulloch was an anaesthetist who had trained at the Children's Hospital of Pennsylvania and was working in adult anaesthesia at the HSC. Odim said that he was agreeable to those proposals, but that he never heard back from Craig.

In contrast to Odim's testimony, Craig testified that he never met with Odim at that time, stating that their one meeting had been in June 1994.

Craig did testify that Tulloch had contacted him to inform him that Giddins had sounded her out about the possibility of her working in pediatric cardiac surgery. Craig testified that he pointed out that Giddins was neither the section head of pediatric anaesthesia nor the department head of anaesthesia. Craig also said Tulloch was aware that the situation was highly charged and therefore she was hesitant about entering into it. Craig also said that he recalled that her name had been put forward at another meeting, possibly by Wiseman or Blanchard. At the time, Craig said that, before he agreed to her working in the PCS program, he would have to check on her knowledge and skills in anaesthesia for pediatric cardiac surgery. Because there was no further discussion of the prospect of Tulloch providing anaesthetic care for pediatric cardiac surgery, Craig did not pursue the option.

Craig also testified that at some point after the program had resumed full service in September, Blanchard had suggested that Swartz take a three or four-month break from the PCS program. Craig discussed this proposal with McNeill, who said that it would be a loss to the service since she regarded Swartz as one of its most capable members. During this same period, the anaesthetists decided that, whenever possible, two anaesthetists would participate in each case.

NOVEMBER 8—THE CASE OF KF

On November 8, 1994, KF, a five-month-old boy, underwent surgery to repair a complete atrioventricular canal defect. In addition, he underwent closure of an atrial septal defect, ligation of a patent ductus arteriosus and repair of his mitral valve.

Witnesses gave differing accounts and differing interpretations of events that took place shortly before the team went on bypass. The controversy revolved around the administration of heparin. In order to conduct bypass, the patient's blood must be treated with heparin to prevent it from clotting. If blood is passed through the heart-lung machine without heparinization, it will begin to clot immediately, with potentially fatal results.

The heparin was measured in advance and kept in a sterile area in the operating room. Generally, a scrub nurse handed the heparin to Odim or his assistant, who would then inject it into a small part of the right atrium, known as the right atrial appendage. From there, the heparin would enter and mix with the blood in the rest of the heart.

About five minutes after the heparin was given, the perfusionists normally measured what was referred to as the activated clotting time (ACT), to ensure that the patient was fully heparinized. A blood sample was injected into what is called an ACT machine. The machine had a timer that measured how long the blood took to clot. Preparation for cannulation generally took place while the ACT was being measured.

According to Wong, in the KF case he noted that Odim was inserting the aortic cannula without having asked for the ACT. Concerned about this, Wong asked Odim if he had already injected in the heparin into the heart. According to Wong's testimony, Odim said that he had not done so and then proceeded to inject the heparin. After waiting until the ACT was measured, Odim finished inserting the cannula. Wong said that it was normal to administer the heparin before inserting the aortic cannula. He also said that while this incident was not as disturbing to him as were the KZ and JB cases, he was left feeling more uncomfortable.

In the notes that she was keeping on problematic incidents during this period, Youngson made the following entry regarding this operation:

> Cannulae in and circuit divided and hooked up all before the HEPARIN given. Usually given by assistant through the R.A. APPENDAGE. Surgeon did not ask for the Activated Clotting Time before he cannulated, de-aired and hooked up the aortic cannula. (Exhibit 20, Document 278 D)

Youngson testified that, during cannulation, she noted that the ACT timer was not ticking. However, she said nothing right away. She was asked who drew it to Odim's attention that the heparin had not been administered.

> I think the perfusionists picked it up. To be honest, I can't remember. I was standing there watching it and thinking, should I say something? I was thinking, well, I will just wait a little longer.
>
> First of all, I couldn't believe that we hadn't done this because it's so routine, it's just one of the things that you sort of do as you go along. I thought maybe I missed it, maybe somehow, maybe I was writing in the chart or something and I just didn't see this. So I didn't want to say anything at that point in time until I was sure that this was actually what was going on. So I just sort of hung back for a minute or two and sort of watched.
>
> But nothing was happening with this machine, it wasn't ticking off the seconds. So, finally, I don't remember who it was that said, hey, we haven't given the heparin. And everybody said whoa, stop. (Evidence, page 8,620)

While Odim did not connect the event with the KF case, he did recall this incident. He gave the following account.

> I do remember an incident in which we had cannulated and the heparin was sort of lying on the nursing tray, and I had indicated to the perfusionist to go on pump, and the nurse mentioned that, oh, we had not given the heparin yet. And so we gave the heparin and then we went on pump.
>
> *Q:* Had you gone on pump without giving the heparin, what are the potential consequences?
>
> *A:* Hopefully, we wouldn't have done that, because the perfusionist's job, before he turns on the pump, is to be sure there is an ACT, and an ACT had not been measured. One of the checks and balances in the system is the perfusionist's responsibility is to be sure that the ACT is greater than 400 seconds before going on pump.
>
> At any rate, if you were to go on pump without heparinizing, you run the risk of clotting the system, pump and cannulas. (Evidence, page 25,805)

Odim said that the standard procedure was for him to give the heparin in the right atrial appendage, except in repeat operations, when the anaesthetist would administer the heparin. He said that, in this case, one of the perfusionists apologized to him. For his part, Odim said, he thanked the nurse for bringing it to his attention and the operation went forward.

While it appeared that the incident with the heparin had no long-term impact on KF's health, it served to further erode relations among team members and confidence within the team.

NOVEMBER 10—THE CASE OF ID

ID was born on November 4, 1994, at the Victoria General Hospital. He was found to be cyanotic at birth and was transferred to the HSC on November 5, 1994. Cardiac catheterization showed transposition of the great arteries, a sizable patent ductus arteriosus with bi-directional shunting and a very small atrial septal defect.

The repair of transposition of the great arteries is a very complex, high-risk operation. At one point, consideration was given to having Dr. Roxanne MacKay come from Saskatoon to assist with the procedure. However, she was unable to do so, for personal and professional reasons.

On November 10, 1994, the day before Ashton Feakes died, ID underwent an arterial switch operation, repair of an atrial septal defect, and ligation and division of the patent ductus arteriosus. Closure of the sternum was delayed because of post-operative bleeding. Odim performed the operation and was assisted by Hamilton. Both McNeill and Reimer provided anaesthetic care. There was a bypass time of three hours and forty-three minutes, an aortic cross-clamp time of one hour and thirty minutes and a circulatory arrest time of ten minutes. Aside from an episode of bleeding at the end of the operation, the procedure went largely as anticipated.

McNeill testified that, during ID's operation, Hamilton played an effective role in helping to control bleeding sites. She said she felt that he had made a positive contribution to all of the operations in which he participated, particularly those of ML and ID.

> It was beneficial. He was another cardiac surgeon who obviously had the expertise of a cardiac surgeon and could form independent judgments. And, you know, had skill in doing specific procedures, as compared to Dr. Hancock who was definitely in an assistant position, being, you know, sort of told—directed, if you will, by the surgeon. I think it is sort of reasonable or is understandable that it would be helpful to have two surgeons in the room who are both trained in the procedures.
>
> *Q:* Okay. That specific expertise, are you able to say if he made any contribution to sort of the atmosphere in the operating room in terms of—I'm not sure we have had this evidence from you, can you comment on that?
>
> *A:* Yes, I would say it was in some ways reassuring. And he, by his nature, is sort of a calm individual, so his response to difficulties is calm and measured, which is always helpful when there is difficulties. (Evidence, pages 13,483–13,484)

In his testimony, Reimer indicated that Hamilton played a very positive role in helping to distinguish between surgical and non-surgical bleeding and addressing them appropriately. Celine Weber, the circulating nurse for the procedure, commented that she thought that Hamilton was able to reduce the stress level that had been common in previous pediatric cardiac operations. She said it appeared at one point that he had actually taken over the case from Odim.

When ID's bleeding was controlled, he was taken to the NICU. On November 16, Hancock and Hamilton closed his chest. Hamilton was surprised to discover that the pediatric cardiac cases were spread between the NICU and the PICU. He told the nurses that he thought it was a foolish policy. He testified that Odim warned him not to say those things because they put people's noses out of joint.

Through his early period of recovery from surgery, ID was given drugs to completely relax his muscles. This medication was stopped and its effects allowed to wear off. On November 23, 13 days after surgery, a nurse noticed that ID was moving his arms, but not his legs. Dr. Oscar Casiro was called to examine ID, who was discovered to have damage to his spinal cord due to what is termed a hemorrhagic infarction. The blood supply to an area of the spinal cord had been diminished. In addition, a hemorrhage had occurred in that area. As a result, ID's lower body was paralyzed and he was paraplegic.

Casiro testified that there were a number of possible causes for the infarction. The area of the spinal cord where the damage occurred normally receives its blood supply from an artery that travels from the aorta. Casiro said that circulation to that area of the spinal cord could have been reduced during the operation, when the aorta was cross-clamped and sutured.

Another possibility involved the umbilical arterial line or catheter that was inserted in ID on November 5 and remained until November 7. The catheter was inserted into the umbilical artery and passed up into the aorta. A clot could have formed in the umbilical artery and then traveled to the smaller artery that supplied the spinal cord, producing the damage. At the time, spinal cord complications associated with umbilical artery catheters had been reported in the medical literature. Casiro testified that ID needed other lines that could have also generated clots of this nature.

The cause of ID's paralysis became controversial in the HSC, when a number of the doctors and a nurse involved in ID's care wrote a brief academic article on the complication. The paper was titled "Spinal Cord Infarct After Arterial Switch Associated with an Umbilical Artery Catheter" and was written by Robert P. Lemke MD, Nnanake Idiong MD, Saad Al-Saedi MD, Niels G. Giddins MD, Cameron Ward MD, Andrew Hamilton MD, Lois Hawkins MN, Betty J. Hancock MD, and Jonah N.K. Odim MD PhD. The article was published in the *Annals of Thoracic Surgery* in 1996, volume 62, pages 1532–1534.

The paper generated comment in the hospital because it appeared to conclude that the umbilical arterial catheter (UAC) caused the paraplegia. The final two paragraphs of the two-page article read:

> On the other hand, the use of UACs has a known, albeit rare association with neonatal spinal cord ischemia. The proposed mechanism of cord ischemia appears related to thromboembolism of the segmental artery supplying the thoracolumbar spinal cord. Clinically silent thromboses have been demonstrated using aortography in 95% of infants with UACs. Furthermore, there are reports of infarction of other major organs such as the intestine and kidneys associated with the position of the UAC catheter tips in sick newborns. Despite widespread use of UACs, cord infarction is presumably rare because of variable collateral blood supply. Indeed, there is a great deal of variability in the patterns and degrees of cord infarction in experimental animals when selected vessels are ligated under tightly controlled conditions. We surmise that this cord was predisposed to a localized hemorrhagic infarction during the surgical repairs because of an unrecognized preoperative ischemic insult related to the use of umbilical vessel catheters [UVC]. We further speculate that the combination of an indwelling UAC and UVC in the inflow and outflow vascular territories subserving the midthoracic spinal cord may have compromised blood flow and increased the potential for thromboembolic occlusion of the blood supply to the anterior spinal artery. The diagnosis of cord infarction and paraplegia in this case was delayed because of a period of postoperative muscle relaxation due to an open chest.
>
> With the widespread use of umbilical vessel catheters in newborns and the increasing trend toward earlier definitive repair of complex congenital heart defects in neonates, the use of peripheral arterial lines may prevent this rare but devastating complication of local spinal cord hemorrhagic infarction. (*Annals of Thoracic Surgery*, 1996;62,1532–4)

Casiro was consulted on the article, which was meant as a case report to be shared with other doctors. The intent was to include Casiro as one of the authors. While he had initially considered participating, he eventually withdrew his name from the article because he did not agree with the conclusions, which he found to be too speculative.

> I had some difficulty with the conclusions in that I thought that the cause of the paralysis, in my view, as I expressed before, was not clear, and that I wasn't so convinced that the umbilical artery catheter in this case could be seen as the major cause, given the fact that the child had surgery on the heart and the aorta afterwards.
>
> So I felt that the conclusions were a bit too skewed towards blaming the umbilical artery, and I would have favored a more balanced view in the speculation part of the article. (Evidence, page 37,945)

Casiro said that if the cause had been the umbilical catheter, one would have expected to see some signs of the damage between November 7, when the catheter was removed, and November 10, the day when ID underwent surgery. Casiro noted that other experts also suggested that the catheter could decrease the blood supply but not sufficiently to cause paralysis. There could, however, have been a second event that might have triggered the paralysis. In his testimony, Casiro pointed out that ID was still moving his lower limbs after the line was taken out, on November 7, three days before the operation. The paralysis followed the operation and the insertion of the left atrial catheter. Casiro said he was not sure which event caused the problem.

Seshia also testified that she believed the proposition put forward in the article on ID was speculative:

> We know [ID] had an umbilical catheter in place. We know that the catheter was above the diaphragm. We know that the catheter came out on day three, okay, of his life. We know that he had his surgery, I think on day five. So the catheter had been removed two days prior to the surgery, and during that period of time he was moving his lower limbs quite all right.
>
> I think the hypothesis in the paper is that perhaps there was some thrombose developing around the catheter which somehow impaired the blood supply to the artery supplying the spinal cord.
>
> *Q:* Thrombose, is that clotting?
>
> *A:* Clot, yes, such that at the time of the surgery, then perhaps there was decreased blood flow going to the spinal cord; and had there been no thrombose around the catheter, no thrombose around the site where the catheter had been, then the blood supply to the spinal cord would have been okay. But what we don't know, or what I don't know is, was there a thrombose? I have no idea if there was a thrombose. (Evidence, pages 33,559–33,560)

In his testimony Odim explained the origin of the article.

> Actually, during this period, [ID] actually was slowly sort of gaining back some recovery. However, the neonatology staff I guess have a M & M or a weekly conference where they present the goings-ons in the neonatology unit, and a couple of the fellows had done a literature search on this problem, and they approached me to sort of get my input, because they had discovered in the literature that this finding has been seen in neonates who have had umbilical artery catheters in place, particularly if these catheter tips were not placed below the level of L3 and L4.
>
> So they came up with four or five papers in the literature describing paraplegia in cardiac surgical babies following UAC line placements. They thought that that was what might have happened in [ID's] case, and it really hadn't crossed my mind.
>
> Initially, my thoughts were that perhaps the line placement in the groin, there may have been some bleeding which bled into the retro peritoneum around the spine and the problem was a mass effect. However, the scan suggested that wasn't the issue, it was within the cord and not outside of the cord, and I really could not explain it until the neonatology fellows had done this search. (Evidence, pages 25,798–25,799)

Odim testified that the neonatologists then looked at the X-rays done after ID's birth. They found that the catheter had been placed in the same area as in the papers they had reviewed.

> So, once they went back and tried to review [ID's] background, and discovered that indeed the UAC catheter was not in an optimal position, they felt that this contributed to the findings. They basically wanted to discuss, from my perspective as a surgeon, whether I had ever seen paralysis in a neonate after open heart surgery, and issues of what happens when you cross-clamp the aorta, issues of what happens in neonatal coarctations, operations that we do all the time. And they were basically trying to find out, from the surgical perspective, what was in the surgical literature with regards neonatal paralysis after open heart.

> *Q:* What was in the surgical literature?
>
> *A:* Basically what they identified. When associated with this cath—there is certainly a report in Edmonton, in fact, from the surgical team there, in which a patient essentially thrombosed a small artery going to the spinal cord, and shortly after heparin, in an open heart procedure, the child had developed paraplegia. They had hypothesized the same rationale.
>
> It was the presence of the catheter causing this thrombosis and infarction in the cord, which probably may not have amounted to much except that when someone gets heparinized, there is a tendency to bleed into these areas.
>
> It's sort of like having a stroke in the brain and the decision, do you put that patient on a blood thinner? And many times if you put a patient that has had a stroke, you can convert it into a hemorrhagic region. And that's the sort of pathophysiology of this area in the spinal cord. (Evidence, pages 25,801–25,802)

The case of ID marked yet another milestone in the collapse of the Pediatric Cardiac Surgery Program. The operation had been conducted without significant incident, yet the final result was tragic. It is beyond the scope of this Inquest to comment on whether or not the hypothesis of the article that was written about ID's complication was too speculative. However, it should be noted that the article did not mention the fact that the catheter had been removed three days before surgery.

By this time, most of the anaesthetists and nurses were inclined to put the darkest interpretations on Odim's actions. The same cannot be said for Seshia and Casiro. Up to this point, they had not voiced any complaints about the Pediatric Cardiac Surgery Program. The case of ID was followed by three more difficult neonatal cases, two of which ended in death. By then, Casiro and Seshia had become very apprehensive of the program and its results.

THE NOVEMBER MEETING WITH MARIETESS TENA CAPILI'S FAMILY

Ben Capili attempted to organize a meeting with HSC representatives following Marietess's death but was initially told to wait until the autopsy report had been prepared. However, the meeting was held in November and by the time of that meeting the autopsy report was not available. The family did not receive the autopsy report until February 1995.

Teresida Tena (Marietess's grandmother) accompanied Ben Capili to this meeting. Sarah Tena declined to attend. Capili said Giddins told them that Marietess's heart was the most complex he had ever seen. Teresida testified that Giddins told them that Marietess had died from fluid in the lungs. She was disappointed that Odim was not at the meeting. Capili said he raised concerns about Odim's ability, to which Giddins responded that he had studied in Boston and Montreal.

THE CASE OF JESSE MAGUIRE

ISSUES

Jesse Maguire was born November 25, 1994, and was immediately diagnosed as suffering from an interrupted aortic arch, ventricular septal defect and an atrial septal defect. He underwent surgery on November 27, 1994, and died while on the operating table.

The issues to which this case gives rise are:

- Should the operation have been performed in Winnipeg or should Jesse have been referred out of province?
- Were Jesse's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Dr. Andrew Hamilton have assisted in this operation?
- Was a cannula inadvertently dislodged during the operation?
- Were all the repairs intact?
- What was the cause of the poor perfusion following the initial repair?
- Were Jesse's parents fully informed about the circumstances surrounding his death?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Jesse Maguire was born at the HSC Women's Centre on Friday, November 25, 1994, at 0829 hours. The child of Laurie Maguire and Richard Shumila, Jesse was delivered at 38 weeks gestation by caesarean section.

On his admission to the nursery at 1100 hours, Jesse was slightly cyanosed and pale. The neonatal resident, Dr. Carr, examined him and found that his pulses and perfusion were good. His chest was clear, with good air entry. Jesse had a heart murmur and an irregular heart rhythm. The heartbeat would occasionally accelerate to a rate faster than two hundred beats per minute. Carr ordered diagnostic tests and consulted with Ward.

An echocardiogram showed Jesse had a number of heart defects:

- an interrupted aortic arch (In this condition, the aorta does not develop completely in the area of the arch. As a result, the aorta is divided into two parts that are not connected to each other, and there is no blood flow through the aorta.)
- a large ventricular septal defect with misalignment (The septum bulged into the outflow tract of the left ventricle.)
- a patent foramen ovale (During surgery, Odim identified this PFO as an atrial septal defect.)
- a bicuspid aortic valve
- an enlarged left atrium
- a restrictive patent ductus arteriosus (PDA).

It was the natural closing of this PDA that caused Jesse's initial problems. As a result, he was treated with prostaglandin to keep his PDA open. Ward concluded that Jesse needed surgery in the immediate future.

In his testimony, Ward said there were three different ways that a heart condition such as this could be approached. He noted that all three approaches were difficult and carried a significant degree of risk. The two approaches with which Ward was most familiar both involved entering the heart from the side and repairing the interruption in the aortic arch. One of these methods involved placing a band on the pulmonary artery to restrict the flow from the VSD, while the other involved simply repairing the arch and then, at a future date, repairing the VSD. Both of these methods required a second repair.

A third approach involved entering the heart from the front and repairing both the VSD and the aortic arch. The difference in this third approach was that to perform the repair from the front, it is necessary to put the patient on bypass.

In his testimony, Ward explained that it was difficult to make clear-cut statements about the comparative risk of these approaches.

> If you do it from the side and you do it with an interposition graph, then it's relatively low risk surgery but you encounter other risks down the track that then increase your risk down the track, in your morbidity and mortality down the track. So you may not play all your cards up front but you're placing yourself at risk down the track.
>
> Whereas to do it all in one procedure puts basically all your eggs in one basket and it puts all your risks up front. You can argue it in numerous ways and it is argued in numerous ways in the medical literature. (Evidence of Dr. Ward, pages 148–149)

Ward recommended that Jesse undergo a two-stage repair.

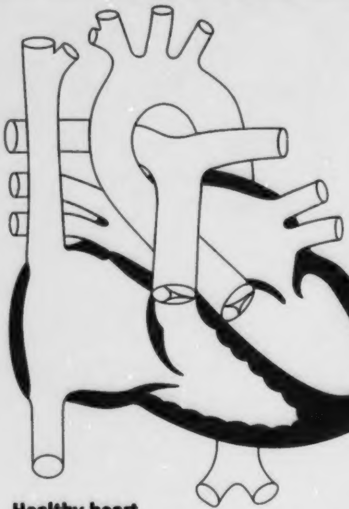
Jesse was transferred to the NICU at 2100 hours on November 25. While his chest was clear, his tongue and lips were becoming more pale and his fingers and toes were becoming cyanotic. During the night, his breathing became increasingly shallow, rapid and irregular. His breathing eventually stabilized; however, he had bouts of irritability.

Casiro and Ward spoke with Jesse's parents that evening. Ward testified that in that conversation he did not suggest referring Jesse out of province. According to Laurie Maguire, Ward told her and Jesse's father that the success rate for these operations was approximately 85 per cent. She also testified that Ward explained the options and indicated that he believed Odim would probably opt for the one-stage approach.

THE DECISION TO OPERATE

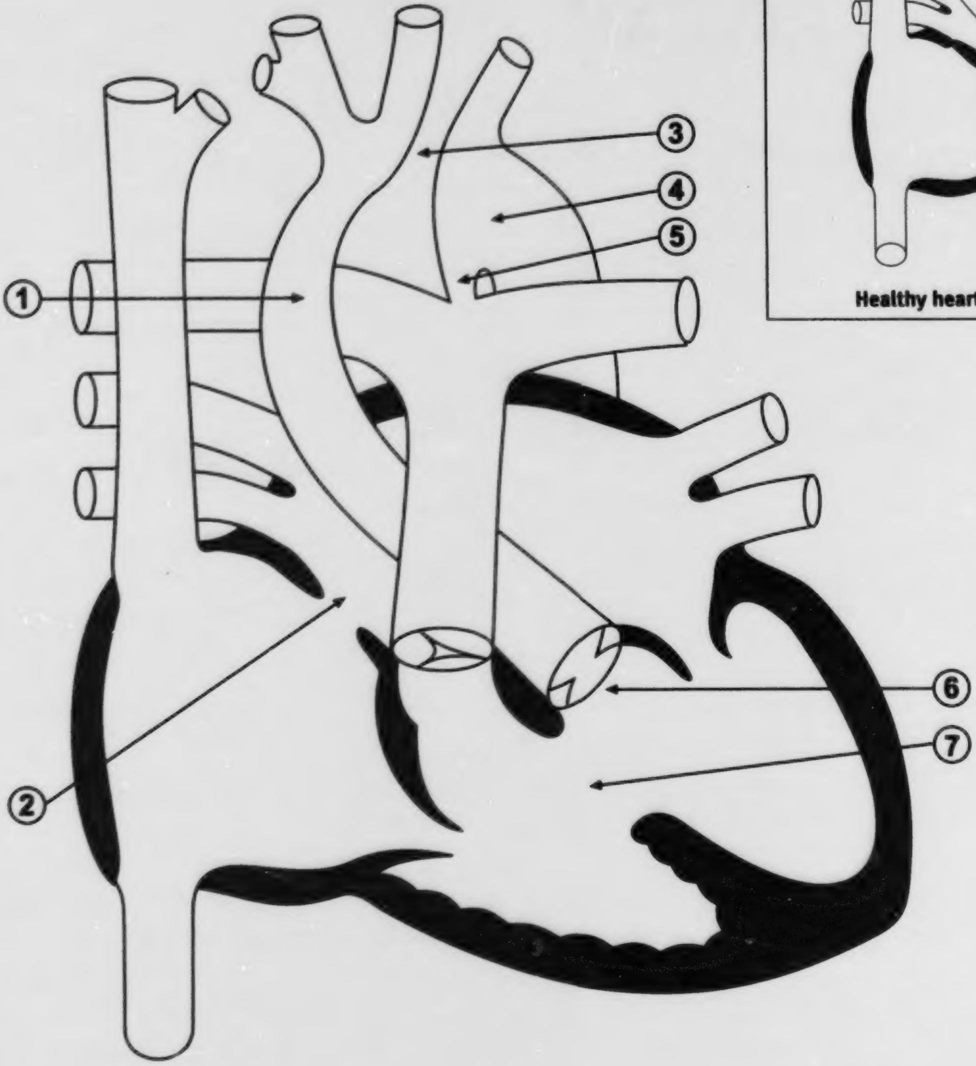
On November 26, at 1600 hours, Odim assessed Jesse. At the time, he thought Jesse had a good blood pressure, good pulses and good urine output. While he concurred with Ward's diagnosis, he felt that a one-stage repair would be appropriate. He said he reached this conclusion because he felt that the overall risks in a two-stage repair were greater than the initial risks of a one-stage repair.

> With the one stage there is a risk with the procedure, but successful procedure enables one to have the hook-up of the descending aorta with the proximal part using biological tissue that can grow with the child and obviate the necessity for additional procedures at that region. (Evidence, pages 25,816–25,817)



Healthy heart

Diagram 8.7 Jesse Maguire – pre-operative heart



1 – Hypoplasia of ascending aorta
2 – Atrial septal defect
3 – Interrupted aortic arch
4 – Descending aorta
5 – Patent ductus arteriosus
6 – Bicuspid valve (identified at post-mortem)
7 – Ventricular septal defect

Odim then discussed his intention with Casiro and Ward. Casiro testified that he had reservations about this approach.

> Well, I asked him why he was choosing that, and I asked him why wouldn't he go for a staged repair, because the first procedure will be low risk, or lower risk than doing both at the same time, and why wouldn't he wait for the child to grow up, be bigger, before attempting the second procedure? So we had a discussion about that.
>
> But he was very adamant that doing it in two stages would involve two, perhaps three operations, timing and so on and so on, and the combined risk was higher than doing it all at once. And I guess my concern arose from the fact that that wasn't what I was used to with the previous surgeon, in general. (Evidence, pages 37,958–37,959)

According to Casiro, Ward expressed the same concerns that he did. Casiro said that Odim's reasoning seemed valid. Casiro said that while he knew of the slow-down in the PCS program, he assumed that because the program had come back to full speed, whatever problems had existed had been addressed.

Odim then spoke to Swartz, who was the anaesthetist on call, and arranged for the operation to be performed the following day, which was a Sunday.

CONSENT

Odim then consulted with Jesse's parents. He testified that he explained the need for surgery, and the nature and risk of the procedure. He said he explained that there were different approaches to the operation. However, he did not ask Laurie Maguire to select the one that she preferred.

> What I did was essentially discuss the risks involved with either approach, and at the end of it, told her what I thought was best, and she accepted it. (Evidence, page 25,836)

In his testimony, Odim said that he had been involved as a first assistant in approximately six such cases over a three to four-year period before coming to Winnipeg. He testified that he did not tell Jesse's parents that this was the first time he had performed this operation as the "main or primary or attending surgeon." (Evidence, page 25,837)

> I felt that the team was competent and could provide an acceptable level of care, ... and the issue of my being an attending for the first time when I came to Winnipeg did not cross my mind. (Evidence, pages 25,837–25,838)

According to his notes, Odim told the family that the mortality rate for this procedure was 10 to 15 per cent. He also testified that he told them the procedure would take between six to eight hours.

Odim was asked if he considered sending Jesse out of province.

> No, that really didn't come to my mind. I knew that interrupted aortic arch lesions are quite rare, and even at the centres that have been in existence for many years, a man 20 years, or a surgeon 20 years out in practice may only come into contact with five cases, just based on the frequency of this type of lesion.
>
> My practice and training was relatively contemporary, and I had seen and worked with a number of surgeons and seen this lesion. So, I was comfortable with the approach to the lesion and the various components of the operation. (Evidence, pages 25,823–25,824)

Laurie Maguire testified that Odim explained the nature of the lesions, the repair and the need for surgery. She said that they did not ask him about his experience with these lesions. Both Jesse's mother and father confirmed that Odim quoted them a 10–15 percent mortality rate for the operation. Richard Shumila testified that Odim indicated that he had not performed this repair before, but he explained that pediatric cardiac surgery was his area of expertise.

NOTIFYING THE OR NURSES

Youngson testified that she received a telephone call from a nurse named Cindy Davidson on the afternoon of November 26. She gave this description of the conversation:

> It was kind of odd. Cindy called me and said, you know, we are doing an open heart, we need the cardiac team to come in. But she said, when Dr. Odim came to book it or phoned to book this case, I asked him if he wanted me to call you, and he said, no, that we would be able to manage.
>
> I went, oh, really. Well, I am coming. You know, we will come. She said, well, she was kind of laughing about it, like this was the most ridiculous thing she had ever heard. Because these were two junior nurses. They have had no experience in cardiac surgery. This was like a neonate.
>
> I am sure they didn't realize how difficult or high risk this particular baby was because they weren't experienced, but they realized that they needed a cardiac nurse. And, in fact, we called in another cardiac nurse as well. Helen Skomorowski came as well. There were two of us that went in for this particular case on a Sunday. (Evidence, pages 8,632–8,633)

Odim testified that he did not think that he ever gave the instructions referred to in Youngson's comment. He testified:

> It's possible that I was asked if Ms. Youngson should be called, and I said, oh, no, that's not necessary. She's one of several cardiac nurses. So I don't think I—if I am understanding this, that I bluntly stated that I didn't want cardiac nurses present. (Evidence, pages 25,849–25,850)

In this testimony, however, Odim indicated that he did not give any special instructions to any members of the team with whom he would be working, in preparation for this operation.

These two pieces of testimony are open to numerous interpretations. The harshest is that Odim did not care if experienced cardiac nurses were present or not for a difficult operation. The most innocent is that Odim felt that, since other operating-room nurses could handle the case, it was not necessary to call Youngson in on her day off. It was, in all likelihood, an innocent, perhaps even a considerate remark. However, it is clear that the nurses did not view it in that fashion. That they did so is not a sign of poor judgment on their part as much as a clear indication of the near-complete lack of respect and trust between the members of the team. This was a legacy of the treatment that the nurses had been accorded from the beginning of February 1994 onwards. By the end of this operation, both the nurses and anaesthetists had even less inclination to give Odim the benefit of the doubt.

HAMILTON NOT CALLED IN

One of the people who should have been called to participate in this operation, but was not, was Hamilton. He testified that this procedure fit the category of operations in which he was expected to assist. He told this Inquest that when he heard about the operation and Jesse's death, he was extremely surprised that he had not been called to assist, although he said he did not speak with anyone about why he had not been asked to do so. In his testimony, Blanchard said he also was surprised that Hamilton had not been brought in to assist. Blanchard testified that he made inquiries after the operation and concluded that Hamilton would have been available to assist, if he had been contacted.

PRE-OPERATIVE STATUS

Swartz conducted a pre-operative assessment that evening. She observed that Jesse's extremities were cool, his heartbeat was irregular and his chest was clear. She assessed him as ASA IV and indicated that he was at risk for arrhythmias, heart block, coagulopathy, paralysis and other neurological injuries. The morning of surgery, Jesse's condition remained relatively unchanged.

There was no evidence presented to this Inquest to suggest that there were any errors in the diagnosis, the pre-operative care or the surgical plan. Several consulting witnesses indicated that the one-stage repair that Odim chose is increasingly common, for the reasons that Odim advanced.

THE OPERATION — NOVEMBER 27

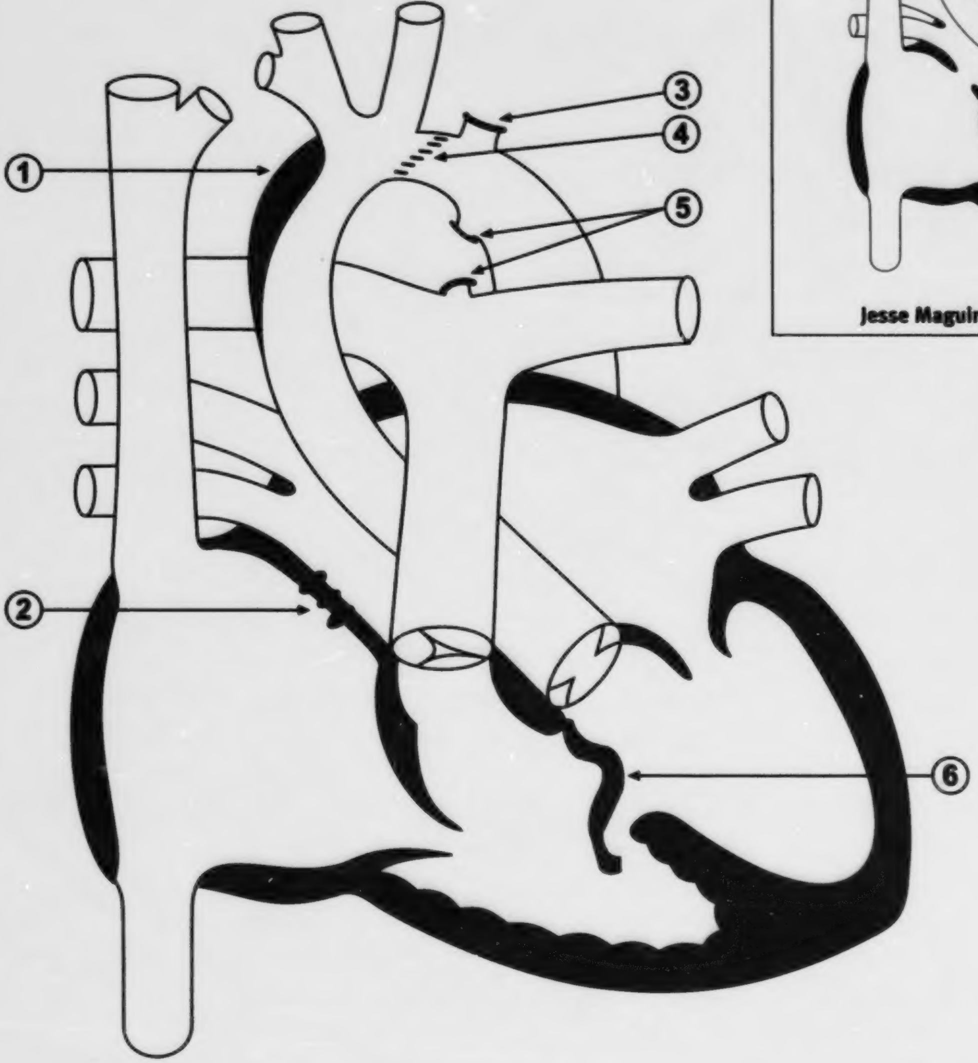
On Sunday morning, November 27, Jesse underwent emergency surgery for expansion of his ascending aorta, repair of his interrupted aortic arch, closure of a ventricular septal defect with a dacron patch, suture closure of an atrial septal defect and closure of a patent ductus arteriosus. Myocardial protection was to be provided by both bypass and profound or deep hypothermic cardiac arrest.

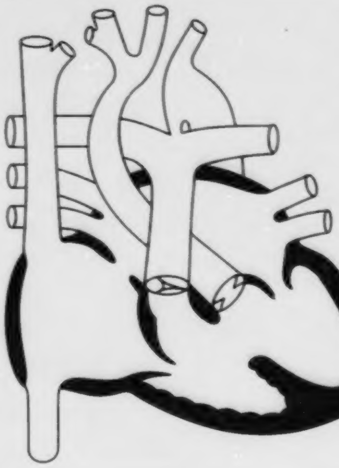
The operating team is set out in the accompanying chart.

TABLE 8.7: Persons involved in the operation on Jesse Maguire, November 27, 1994

OR team member	*Persons involved*
Surgeon	**J. Odim**
Surgical assistants	**B.J. Hancock, D. Miltenburg (resident)**
Anaesthetists	**J. Swartz (relief provided by R. Graham and L. Patel), L. Stanko (resident)**
Scrub nurse	**C. Youngson, M.J. Wasney**
Circulating nurses	**H. Skomorowski, C. Davidson**
Perfusionists	**M. Maas, D. Smith**

Diagram 8.8 Jesse Maguire – post-operative heart





Jesse Maguire – pre-operative heart

1 – Patch expansion of ascending aorta
2 – Suture closure of atrial septal defect
3 – Ligated and divided left subclavian artery
4 – End-to-end repair of interrupted aortic arch
5 – Ligation and division of ductus arteriosus
6 – Buckled ventricular septal defect patch

TABLE 8.8: Length of phases of the operation on Jesse Maguire, November 27, 1994

Phase of the operation	*Time taken*
Induction	**2 hours 29 minutes**
Bypass	**6 hours 12 minutes**
Total circulatory arrest	**2 hours 49 minutes**
Total surgical time	**11 hours 7 minutes**
Total operating-room time	**13 hours 59 minutes**

To undertake the repair, the team inserted cannulas into Jesse's blood vessels, using double-arterial cannulas (one in the ascending aorta Y-connected to one in the pulmonary trunk) and a single venous cannula (in the SVC). Intermittent cold blood cardioplegia and deep, hypothermic, total circulatory arrest were to be used for myocardial protection. At 1247 hours, the anaesthetist applied ice to Jesse's head to protect his brain. Bypass was then started. Solumedrol was given intravenously at 1300 hours, conceivably to decrease swelling of the brain, or cerebral edema, and total circulatory arrest (TCA) was then instituted. At that point, the cannulas were removed to give the surgeon a relatively clear operative field. While cannulation is always a significant factor in any open-heart procedure, it is particularly significant in the repair of an interrupted aortic arch, since the aortic cannula is being inserted into the very vessel that is to be repaired.

Repairing the VSD while on TCA

After repairing the aortic arch and ligating the left subclavian artery to improve the mobility of the descending aorta, Odim went on to repair the VSD and ASD while Jesse was still on TCA. Swartz testified that she was surprised by the decision to repair the VSD on TCA, since she thought that the team would return to what is termed low-flow bypass for this repair. Low-flow bypass differs from regular bypass, in that there is a lower flow of blood through the patient and the low temperatures of circulatory arrest are maintained. Low-flow bypass does provide some perfusion of the body, in contrast with TCA when there is no blood flow.

Swartz testified that she spoke to Odim about this decision not to return to low-flow bypass for the VSD repair.

> After Jesse had been on circulatory arrest for 45 minutes, I said to Dr. Odim—I can't remember the exact words that I said, but I basically said, aren't we going back on low flow? And he said no. And I said, well, we have been on, you know, deep hypothermia for 45 minutes. And he said to me, are you worried? And I said yes. And he said me too. And that was it. So, he didn't go back on low flow and we continued on deep hypothermic circulatory arrest for the duration of the repair. (Evidence, pages 16,250–16,251)

Swartz was afraid that there was increasing danger of neurological damage as a result of the length of TCA. Youngson confirmed the exchange between Odim and Swartz. According to Youngson, Swartz asked Odim if he was repairing the VSD. He replied that he was and then asked if she were worried. She said yes, to which, Youngson testified, he said, "'I am doing it' or something like that. He made a kind of offhand kind of remark and kept on working." (Evidence, page 8,637)

When the repair was finished, the cannulas were reinserted and Jesse was placed on bypass at 1532 hours. He had been on TCA for 102 minutes. It had taken Odim about 57 minutes to repair the VSD while the child was on TCA. Consulting witnesses who prepared reports for this Inquest indicated that this was a dangerously lengthy period of time for TCA. Cornel wrote that with a TCA of this length, "there would have been a probability of brain damage." (Exhibit 353, page 65) In the report prepared by Duncan and Cornel, it was noted that it would have been preferable to repair the VSD on low-flow bypass. Hudson wrote that the 102-minute period was exceedingly long and would have been likely "to cause significant morbidity and/or mortality in a neonate." (Exhibit 307, page 11.3) Soder testified that the time of the initial bypass "would probably have produced a bad outcome." (Evidence, page 44,203) Soder, too, thought it would have been appropriate to repair the VSD on low-flow bypass.

Odim was asked why he chose to repair the VSD on TCA. He responded:

> Because I felt that it would be easier to do. The field was bloodless, we did not have the cannulas in the way in this small baby, and I thought it would be easier to get the VSD accomplished under circulatory arrest.
>
> *Q:* What do you mean by easier?
>
> *A.* Easier in the sense that, from the technical point of view, in a very, very small baby, the advantage of circulatory arrest is that you don't have the cannulas in your way, and you don't have venous return coming back to the heart, so the field is bloodless. (Evidence, page 25,868)

Odim testified that it took between 50 and 90 minutes for him to complete the repairs on TCA. He was asked if it would have been possible to repair the VSD and the ASD on bypass. In regard to the VSD, he said:

> Yes, I think that might have been an option. I don't know how easy it would have been to do it on bypass, in terms of the technical aspect of it in a very small baby, the issues of the cannula clutter and the venous return and the visualization and the exposure. So there is a trade off. (Evidence, page 25,873)

He noted that while the ASD could have been closed on bypass, closing the ASD only added two or three minutes to the total time on TCA. Odim was asked whether or not he recalled Swartz's questioning of his decision to undertake the VSD repair during TCA.

> Yes, Dr. Swartz the anaesthetist as well as the perfusionist did point out to me the circulatory arrest time, and there was a comment to the fact that, isn't this kind of long and you are doing the VSD, and my reply was, yes, it is long, and we do have a VSD to do. And that was the extent of the conversation. (Evidence, page 25,885)

When asked why he continued with the VSD repair under TCA, given the worries over time, he said:

> Because it was my preference for exposure reasons and my experience to get this done under one circulatory arrest period. I do know that some of these periods will exceed 60 minutes, 70 minutes or even 80 minutes, but I was trying to weigh the potential difficulty of doing it under low flow with the blood return and exposure issues, and at 40 minutes felt that the exposure was better and that it would be easier to tackle the VSD without the interference of the cannulas and the return. (Evidence, page 25,886)

In his testimony Odim said that it had always been his intention to perform the major repairs while Jesse was under TCA. In a pre-operative note in the chart, however, Odim had indicated that he in fact intended to use deep hypothermic circulatory arrest with low-flow bypass. He maintained, in fact, that once the major repairs were completed, he went on low-flow bypass for the completion of the operation. The team went back on bypass at 1532 hours.

The dislodging of the cannula

Youngson testified that at approximately 1630 hours, while Jesse was being rewarmed, she heard a member of the operating team gasp. She turned to see that the aortic cannula had been dislodged. With the removal of this cannula, Jesse was no longer receiving blood from the bypass machine. Michael Maas, the perfusionist, turned off the bypass machine to stop it from draining blood from the child. According to Youngson:

> At that point in time, there is this concerted effort by the two surgeons to get this cannula back in. They were having a very, very difficult time getting this cannula in. They were just taking it and trying to shove it back into the aorta, any way just to get it back in and get back on pump. To me that was their objective, to just get this cannula in, and let's get this baby back on bypass. Neither one of—
>
> *Q.* Just taking it and trying to shove it back in?
>
> *A.* Neither one of them could seem to do this. I know that Odim tried a couple times, couldn't do it. B.J. took it away from him and said, let me try. And she tried a couple of times, she couldn't get it in. Sort of back and forth like this. They were rough. (Evidence, page 8,641)

At the same time, Youngson testified, she was suctioning blood from the operative field in an effort to assist the surgeons to recannulate Jesse's aorta. By Youngson's estimate, it took approximately five minutes to re-insert the cannula.

In notes that she made right after the operation, Youngson wrote:

> During the rewarming process the Aortic cannula was dislodged and fell out. Both the surgeon and the assistant (DR. Hancock) struggled for 6 or 7 minutes to replace the cannula. They were very disorganized and panicky. They argued with each other and grabbed the cannula and instruments from on [sic] another and it was very obvious that NEITHER ONE HAD THE SKILL OR EXPERTISE TO HANDLE THIS SITUATION. [Capitalization in the original.] Dr. Odim was extremely rough, "jamming" the cannula in again and again. Prior, to this event there had been some problems with the purse string sutures breaking. Instead of replacing them the surgeon asked the scrub nurse to shorten the rubbers on them so that they were now approx. 2.5 to 3 cm. long and much too short to work with. It was noted that the surgical field was extremely messy and unorganized throughout the case.
>
> During the time that the surgeon was trying to reinsert the cannula these purse strings hampered their efforts because they were so short. As well there was almost no communication from the surgeon to the perfusionist and he (Mike Maas) had to resort to asking the scrub nurse what was taking place. It fell on the scrub nurse to inform the perfusionist to de-air the cannula again and again during this event, and to keep him informed as to what was happening. (Exhibit 20, Document 278 D)

Swartz corroborated this account. She testified that the surgeons were scrambling to control the bleeding and to re-insert the cannula.

> Well, one person would try, then the other person was trying, then the other person would try. It was a very disorganized surgical field. And there was bleeding, they were suctioning, and it was—they were trying to push it back in. (Evidence, page 16,275)

During this period (which she estimated lasted five to seven minutes) Swartz was transfusing blood to Jesse through an intravenous line.

In his testimony, Maas said that the cannula became dislocated at 1630 hours. He testified that while he did not know how it became dislodged, there could have been no reason for it being removed at that point in the operation. He said Odim stated that the cannula was out.

> So, obviously, for me that is a major event, and we have to shut the pump and all the systems down, without exsanguinating the patient.
>
> Because if I continue to leave the venous line open, and I have no in-flow, I will drain the patient totally of blood in seconds. (Evidence, pages 7,051–7,052)

The anaesthetic record indicates that the total time from the cannula coming out and its re-insertion was six to eight minutes. Swartz testified that she did not record the times as the events were occurring, but made the entry after the end of the operation by checking the computer readings from the anaesthetic machine and determining that the cannula had been dislodged at 1630 hours.

The perfusion record indicated that the cannula was out for approximately one minute. Maas testified that the entry in the perfusion record was not made while attempts were being made to re-insert the cannula, but after the problem had been resolved. Neither he nor the other perfusionist, Dave Smith, had recorded the time, and the figure of one minute was an estimate that Smith had entered into the record. This estimate was based on Maas's guess that the cannula was out for one to two minutes. Maas said that, after reviewing the anaesthetic records, he was satisfied that the cannula was more likely out for five to six minutes. The time on the anaesthetic record is likely more accurate, given that it was determined retrospectively from computer-generated records.

Maas also testified that it appeared that Odim and Hancock experienced difficulties reinserting the cannula:

> You could tell they were struggling at the table, as far as we could tell, to get this thing back in. They are dealing with very, very small areas, first of all, very small exposures, very small vessels. And already it has a major repair on the vessel, the suture lines.
>
> It has had two cannulas sites in the aorta, when they initially cooled the patient and the going back on again. I can imagine that would be very difficult to get that back in. (Evidence, page 7,055)

Maas said that this was the first time in 18 years that he had witnessed such an event. He further testified that, after the operation, he had asked Odim what had happened.

> And he had no explanation for how it became dislodged. And we asked him, I asked him what happened next. And he explained there was a rent in the aorta, and he had to repair that, and it made his initial repair inadequate, I guess, and that's why we had to go back and do a second circ arrest to repair that. (Evidence, pages 7,072–7,073)

(Odim's subsequent testimony suggests that in his response to Maas's question he was referring to a later event in the operation.)

The testimony of Irene Hinam and Dave Smith corroborated the account of Maas, Youngson and Swartz.

In their testimony, Odim and Hancock surprisingly said that they could not recall the cannula being inadvertently removed. Nor could they recall the events described by Swartz, Youngson, Hinam, Smith and Maas. Odim was asked if he could help explain the difference in the evidence that he and Hancock gave, compared with the evidence from the nurses, perfusionists and anaesthetist.

> I really can't explain it, I've looked at these records and the problem I have is I'm trying to match up my recollection of the events with two different records and I'm getting confused as I try to do that. (Evidence, page 25,991)

From the weight of the evidence that has been presented, including both the testimony and the records kept by the anaesthetists and the perfusionists, it would appear that this event did, in fact, happen. At 1630 hours, the aortic cannula somehow became dislodged. From this time on, a series of problems occurred that eventually led to Jesse's death in the operating room.

Once the cannula was reinserted, shortly after 1630 hours, Jesse remained on bypass until taken off at 1802. However, the team was not able to get proper blood pressure readings from the lower part of Jesse's body. This problem suggested that there was a lack of blood flow to Jesse's lower body. A number of steps were taken to determine the reason for this poor blood flow. It was suspected that the aortic cannula itself was creating the blockage. In a post-operative letter to Jesse's doctor, Odim wrote, "There was a problem with obstruction from the arterial cannula which is not unusual for babies this size with a 5 mm aorta." (Exhibit 8, page MAG 21) This obstruction from the cannula meant that it was necessary to remove the cannula. However, when it was removed at approximately 1810 hours, there was no improvement in lower body blood pressure.

In his operative report and in his testimony, Odim stated that he believed the purse-string tourniquets probably caused the continued obstruction. These were tourniquets that he placed in the aorta when he removed the cannula (to close the hole through which the cannula had been inserted).

It was agreed at the time that the only option was to return to bypass and attempt to find the obstruction to blood flow and repair the cannulation site. To go back on bypass, it was necessary to reinsert the cannula. Odim once more experienced difficulties with cannulation. In his evidence, he said:

> [W]e struggled to get the cannula back in. There is no question I felt at that time took an eternity. We simply could not get the aortic 8 French catheter back in and seat right. Multiple times it went in and came out we could just not get it to sit straight in the lumen, and ultimately after several minutes I had to go with a larger cannula to get it back in the aorta and go back on pump, and in the course of doing that, we disrupted the anterior suture line of our repair and had to repair that site and, unfortunately, that certainly played a role in Jesse's demise. (Evidence, page 25,992)

According to Odim's testimony, the cannula was finally re-inserted at 1832.

According to Swartz, at this point Odim said he had torn the original repair of the aortic arch. The team went back on bypass at 1834 hours. According to Odim:

> Once we got back on bypass, it became quite clear that with the larger cannula in and the friable tissue around it, that we essentially had encroached our anterior suture line.
>
> *Q:* Sorry, go ahead and finish it.
>
> *A:* And that we had an area of our anterior suture line that needed to be repaired. And the question was, can we repair this without having to use circulatory arrest? (Evidence, page 26,057)

Odim made the decision to go back on TCA to repair the tear in the anterior (or front) of the original repair to the aorta with pericardium. While this carried considerable risk for Jesse, it was felt that there was no other option available to the team. TCA was re-instituted at 2015 hours.

During the second period of TCA, Swartz was relieved by another anaesthetist and left the OR. While she was out of the OR, Swartz spoke with Ward and informed him of the first unplanned dislodging of the aortic cannula at 1630 hours. She testified that after she returned to the OR, Ward subsequently entered and spoke with Odim. While she could not recall the specifics of what Odim told Ward, she did recall that Odim did not mention the dislodging of the aortic cannula. In his testimony, Ward said that while he could not recall the specifics of what he was told by Swartz and Odim, he had had trouble at the time reconciling what he had been told.

The repair was redone while Jesse was on TCA for an additional 67 minutes. He was placed on bypass once more at 2122 hours. His body was then rewarmed and efforts were made to start his heart beating once more. These efforts included defibrillation, pacing and treatment with a variety of drugs, including adrenalin. However, his heart never started beating on its own. Odim, Ward, Swartz and Casiro concluded that it was not possible to resuscitate Jesse. He died in the OR at 2239 hours.

Swartz testified that, following Jesse's death, Odim said to her that he should have been more meticulous in his cannulation. Odim said that he recalled speaking with someone after the operation and stating that the cannulation had been the Achilles heel of the operation.

Youngson also testified that after Jesse had died, Odim spoke to Ward about informing the parents.

> Dr. Odim looked over at him, and he said, I guess you will have to go up and tell the parents that Jesse has died. He said I think it is best that we just say that we couldn't wean Jesse off of bypass, and best not to mention that, you know, we had had this problem with the cannula. (Evidence, page 8,662)

Swartz confirmed this conversation. In her testimony, she said that "Dr. Odim suggested that it would—they should say that they had trouble weaning from bypass." (Evidence, page 16,330) She testified that she was surprised by this comment:

> The reason I was is because when a child dies, it is a very stressful situation for everybody, including the family. And so the question is, when do you—how do you approach telling the sort of the sequence of events or the true events that have taken place. And you don't want to hurt them. Because you are not sure how to do this, probably the best thing to do is just say it. But I was, I thought, how do they know what to say to the family? How can they actually say this to the family and when will the family actually find out what happened, and will the family ever find out what happened? And those were the thoughts that were in mind at the time. (Evidence, page 16,331)

Youngson was similarly upset by the conversation.

> I was shocked. I mean, Jesse Maguire was my worst nightmare come true. This was what I had been afraid of all along, that something like this was going to happen, and here it had happened.
>
> And whatever, what little respect I had for this surgeon at that point, it was dropping by the month or by the week. That was it, I lost all respect for him, because I felt you screwed up here, and you don't even have the courage to go out and admit it to these parents. You don't have to go out and say I screwed up, but you can at least be honest with the parents and tell them about the problem. (Evidence, page 8,665)

In his testimony, Ward testified that he had asked Odim what he thought the parents should be told.

> And he said, Well, why don't you just tell them that—basically they'd been kind of pre-warned that things weren't going well. So I think he suggested, from memory, that we just inform them of basically the fact that Jesse hadn't come off pump.

> *Q.* Um-hmm.
>
> *A.* And then he would deal with the other stuff or we would deal with the other issues later, the technical issues and why there were problems coming off pump and exactly what the problem was. (Evidence of Dr. Ward, pages 105–106)

Ward said it was standard not to go into the technical issues at that point. Martin Corne, the lawyer representing Jesse's parents, suggested to Ward that Odim specifically told Ward not to tell the parents about the cannula. Ward testified:

> I can't remember that specifically, but I think I've said on more than one and probably more than three occasions already that it's customary for us to go out and tell the parents that the child has died and that's usually enough for the parents to cope with at once. To talk about the technical issues at that first instance is usually not useful and it goes right over their head.
>
> *Q.* Whether it's useful or not, Sir, did Dr. Odim tell you not to tell the parents about the cannula—the problem with the cannula?
>
> *A.* I can't recall that specifically. What I'm trying to indicate to you is what we usually say is, Okay, I'm going out there. What do you want me to say to the parents? Now, specifically what was said, I can't honestly recall. But that wouldn't surprise me because it's not something that you usually address in the first instance. (Evidence of Dr. Ward, pages 187–188)

Odim testified that he could not recall this conversation. He testified that he did speak with Jesse's parents that evening.

> I don't remember the specific wording, but the gist of the conversation was that we had done the operation, things were looking good, the heart was beating strongly, and there seemed to be a problem at the cannulation site, and I took the cannula out and we had to repair that area which required going back on bypass.
>
> After we had done that, essentially the heart was not strong enough to sustain things, and that was sort of the gist of what I told Mrs. Maguire. She was obviously distraught, and I welcomed her to, at any other time, if she wanted to talk some more about things, but that's the gist of what I told Ms. Maguire when I got out of the operating room and met her. (Evidence, page 26,092)

Richard Shumila and Laurie Maguire had spent most of the day of surgery at the HSC. At approximately 1930 hours, Laurie Maguire went to the Women's Pavilion for medication. While she was away, Ward came to speak with the family. According to Richard Shumila, Ward said that there were problems weaning Jesse from bypass. Ward then went to the Women's Pavilion and informed Laurie Maguire. This was the first indication that Jesse's parents had received that Jesse's operation was not going well.

Laurie Maguire said that between 2300 and 2330 hours, Odim, Ward and Casiro came out with the news that it had not been possible to wean Jesse from bypass. She testified that "Dr. Odim was fairly cool, but Dr. Ward was crying. And, well, they—I mean it was obviously traumatic for them as well." (Evidence, page 4,155) She testified that no one spoke to her about cannulation at that time. She also testified that Ward said it would be appropriate to arrange a meeting in approximately six weeks time to discuss the issues surrounding Jesse's death. However, she said that she chose not to follow up on that offer at that time.

POST-MORTEM FINDINGS

An autopsy ordered by the Chief Medical Examiner was conducted by Phillips on November 30, 1994, with Odim and Ward attending the examination of the heart. Phillips had noted that, according to information related to her by Swartz, there had been a dislocation of a cannula at one point in the operation before the child was weaned from bypass. This was the event that the witnesses said occurred at 1630 hours. When Odim heard what Phillips had been told, he told her that her information was not accurate.

The autopsy indicated that the repairs undertaken by Odim were intact. However, the heart had suffered severe ischemic damage that had led to death. The report detailed extensive myocardial ischemia and contraction band necrosis.

Phillips also noted that the septal leaflet of the tricuspid valve had been tethered to the pledget closing the VSD. Because Jesse's heart never started beating after surgery, it is not possible to determine the impact that this would have had on the functioning of his heart. (The tethering is not depicted in Diagram 8.8)

The autopsy also left a question as to whether or not the initial blockage of the aorta was ever completely addressed. In the course of the autopsy, Phillips was unable to push a probe through the aorta past the site of the anastomosis. However, when she opened the aorta, she could find no obstruction.

Ward testified that, while it appeared that the VSD had been closed appropriately, he had concerns about the repair to the aorta.

> And the arch repair by then—the probe that was put through didn't pass through easily and as it passed through the transverse arch or the—I can't remember – I think—or the repair site anyway, it didn't pass easily, and I wasn't totally convinced at that stage that everything was open. The trouble is that the specimen in that circumstance has not got blood flowing through it so it's not stretched; it's, if you like, collapsed down.
>
> *Q.* Um-hmm.
>
> *A.* So the tissues and artificial tissue and patches will fold without the pressure of the blood within it.
>
> *Q.* Um-hmm.
>
> *A.* So you can—your probe can get caught up on folds, if you like, of artificial tissue and/or real tissue and not slide through. But generally, if you work your way through, you can get it through. But we weren't able to, from memory, get it through just passing it through, but when it was opened right up, it looked patent. So it may have been just—
>
> *Q.* Um-hmm. What does that mean?
>
> *A.* Well, it may have been just snagging up on tissue planes and it certainly looked as though it was probably potentially open. (Evidence of Dr. Ward, page 99)

Taylor was asked if he felt the second repair was properly done. He answered that "the second repair looked to be about as good as one might expect, because the opening is the same as the ascending aorta, the vessel that is supplying that, sort of leading into the anastomosis." (Evidence, page 43,298) He was then asked about Phillips' inability to pass a probe through the aorta.

> Well, a 3 millimetre probe would be about the right size for the circumference that was measured. We measured circumference of 1 centimetre. So if everything was flat and there were no obstructions, then I would have expected a 3 millimetre probe to go across the anastomosis.

> Having a probe get caught up like that, in my experience, usually is a result of a fold or a flap, that when you push the probe into something it gets caught up in it. So that suggests to me that maybe there was some flaps or folds as a result of the anastomosis repair. (Evidence, pages 43,300–43,301)

He said that Phillips's observation that there was a fold in the pericardial patch was one potential explanation. However, he said, it was also possible that the probe had become caught in a buckling of the inner lining of the aortic anastomosis.

Taylor also raised issues about the VSD patch. In his report Taylor wrote:

> [T]he VSD patch was buckled to convexly project into the left ventricular outflow tract. These are anatomical substrates for proximal obstruction that may have contributed to the child's cardiac failure. (Exhibit 336, page 11.1)

In her testimony, Phillips said that at the time she examined the heart, it appeared to her that the VSD patch was intact. In his testimony, Taylor testified that he could not state whether or not the buckling was an operative problem.

FINDINGS

As noted at the outset, this case gave rise to the following questions:

- Should the operation have been performed in Winnipeg or should Jesse have been referred out of province?
- Were Jesse's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Dr. Andrew Hamilton have assisted in this operation?
- Was a cannula inadvertently dislodged at 1630 hours?
- Were all the repairs intact?
- What was the cause of the poor perfusion following the initial repair?
- Were Jesse's parents fully informed about the circumstances surrounding his death?
- What was the cause of death and was it preventable?

Should the operation have been performed in Winnipeg or should Jesse have been referred out of province?

■ Finding

The evidence tends to suggest that the team in Winnipeg should not have performed Jesse's surgery. To once more make use of Soder's assessment, the evidence suggests that:

> **the skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations.** (Boldface in original) (Exhibit 345, page 8)

This operation required considerable skill. Cornel called it a high-risk procedure, with a fatality rate of 15 per cent. In this case, Cornel concluded that "Technical errors were made in the course of this operation which precluded a successful outcome." (Exhibit 353, page 67) Specifically, he was referring to the problems with cannulation. In addition, Cornel stated that this condition is so rare that it takes a surgeon many years to gain experience in the appropriate care of such patients. In their joint report, Duncan and Cornel wrote:

> Other technical issues relate to our questioning a relatively inexperienced team's capabilities to do technically difficult surgery on a neonate with a small aorta. Was the option of a remote referral provided? (Exhibit 354, page 14)

One can point to the following areas as evidence of the problems with the operation as performed in Winnipeg.

- ***The length of the first period of TCA.*** Consulting witnesses who appeared before this Inquest indicated that a TCA of over one hour was almost certain to lead to severe damage to Jesse Maguire, even if the rest of the operation had gone smoothly.
- ***The decision to repair the VSD on TCA.*** Given the length of time it took to repair the aortic arch, the evidence suggests that Odim should have conducted this repair on low-flow bypass. By failing to do so, he contributed to the overly long period of TCA.

In his testimony on this point, Cornel stated that he would repair a VSD on TCA only if he could keep the entire period of time on TCA under 45 minutes. In Jesse's case, the total initial period of TCA was 102 minutes. When Odim decided to proceed with the VSD repair, Jesse had apparently already been on TCA for over 40 minutes. Cornel acknowledged that it is easier for the surgeon to perform this portion of the repair under TCA, but it is also apparent that there is no benefit to the patient when the TCA is as long as it was in this case.

- ***The difficulties in recannulating Jesse's aorta at 1630 hours.*** Recannulation, in all likelihood, initiated a series of events that led to the need to put Jesse on bypass and TCA for a second time, with fatal results.
- ***The lengthy period of time that preceded the decision to separate from bypass and remove the cannulas.*** Hudson's report on this point is telling. He writes:

> The attempts to separate from the first session of CPB lasted from approximately 1615 to 1800. If the team had diagnosed and treated the problems encountered during this time more expeditiously, the total time on CPB would have been shortened, which might have favourably influenced the outcome. (Exhibit 307, page 11.6)

In his testimony, Hudson was even more explicit, stating that during the 105 minute period the team determined that it could be the cannula that was causing the obstruction. That being the case, they decided to go off bypass and remove the cannula. After pointing out that in the chart Odim had observed that this was a known problem, Hudson testified, "my point there was that if this is a known problem, that it shouldn't have taken an hour and three quarters to develop a plan of management to attack it." (Evidence, pages 40,042–40,043)

- ***The difficulties surrounding the removal of the cannula at 1810 hours.*** Odim indicated that he believed that the sutures he put in place after removing the cannula at 1810 hours might have continued the obstruction that he thought had originally been caused by the cannula. This required him to re-insert the cannula.

- ***The difficulties in recannulating Jesse's aorta at 1842 hours.*** During recannulation, the initial repair was torn.
- ***The length of the second repair.*** Witnesses testified that the length of the second period of TCA placed Jesse at considerable risk.

Were Jesse's parents provided with sufficient information to allow them to give informed consent to the procedure?

■ Finding

Jesse's parents were apparently aware of Odim's relative lack of experience in performing this type of surgery in an unsupervised setting. Richard Shumila recalled Odim telling them that he had not done this type of procedure before, but that cardiac surgery was his specialty. The difficulty was, of course, that like most parents (and patients), it is difficult to know how to evaluate this information.

However, the parents were not told of the program's recent problems; nor were they offered the option of transferring their son out of province for surgery. In their testimony, Cornel and Duncan stated that it might well have been possible for Jesse to have been transferred safely. This should have been discussed with his parents. This evidence tends to suggest that Jesse's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Should Dr. Andrew Hamilton have assisted in this operation?

■ Finding

This was a high-risk operation that fit the criteria under which Hamilton was expected to assist Odim. Both Hamilton and Blanchard testified to this fact. Unfortunately, as noted earlier, the evidence is not clear as to whether this instruction had been properly communicated to Odim or to the rest of the PCS team.

Was a cannula inadvertently dislodged at 1630 hours?

■ Finding

While Odim and Hancock could not recall this event, the testimony of the anaesthetist, perfusionists and nurses, coupled with the anaesthetic and perfusion records, all suggest that this event took place.

Were all the repairs intact?

■ Finding

Phillips and Soder, in their reports, concluded that all of the repairs were intact. It is not possible to argue with that finding. However, that simply means that the repairs had not failed.

Unfortunately, the repairs were never tested, as Jesse died without his heart having started to beat on its own.

What was the cause of the poor perfusion following the initial repair?

- Finding

It is not possible to provide a definitive answer to this question. In his report, Cornel wrote that:

> The difficulty with the aortic cannulation site may have been the result of poor positioning of the cannula, an unsuitable cannula or overly generous purse string sutures. (Exhibit 353, page 66)

In his testimony, Taylor said:

> If the cannula or catheter is placed in a vessel that it may be too big for, it can strip the inner lining of that vessel and they form flaps as they are stripped back by the cannula or catheter. (Evidence, page 43,292)

Taylor said that the risk of this occurring increases if the cannula is inserted in a hasty manner, or if the cannula is too large.

The evidence from the autopsy also suggests that even after the initial repair, the aorta may have been partially blocked. The evidence suggests that, even if the aortic arch had been successfully repaired before Jesse died, it may not have been functioning properly before Jesse was put on bypass for the second time after 1830 hours.

All of the possible explanations for the subsequent problems with blood flow and pressure relate to surgical actions.

Were Jesse's parents fully informed about the circumstances surrounding his death?

- Finding

There are two issues that require comment about the information made available to Jesse's parents. The first is "what was told to them on the night of Jesse's death?" The second is "what was told to Jesse's doctor, Dr. S. Collison?"

As noted earlier, both Swartz and Youngson testified that they heard Odim tell Ward not to tell the parents about the problems with cannulation that occurred during the procedure. Swartz and Youngson interpreted this statement as an attempt to cover up the events that had taken place during the operation. Given their experiences, both in the previous year and on the day of the operation, it is not surprising that they put such a negative interpretation on Odim's comments. Neither Odim nor Ward were able to recall the instruction not to mention the problems with cannulation.

It should also be noted that Swartz and Odim gave Ward differing accounts of what had transpired during the operation. This placed Ward in a difficult position. It would not have been possible for him to determine accurately which account was correct at that time; nor would it have been appropriate to provide the parents with the account of either Odim or Swartz alone. It also would have been inappropriate for Ward to have advised the parents at that time of the conflict in the views of the surgeon and the anaesthetist. The best that Ward could do was to advise the parents that Jesse could not be weaned from bypass, and that more information would be shared with them when they were ready. This is what he did.

The evidence would suggest, therefore, that Ward's actions were appropriate to the moment. Similarly, if Odim's advice was simply that, on that evening, the parents should not be given detailed information about the events surrounding Jesse's death, then it was an appropriate instruction. However, the instruction was appropriate only as long as it was accompanied by an intention to be forthright with Jesse's parents when the opportunity presented itself.

Jesse's parents did deserve to receive a full accounting of the events surrounding Jesse's death. The evidence suggests, however, that they did not receive such an accounting.

In his November 28 letter to Collison, Odim neglected to mention the inadvertent decannulation that took place at 1630 hours. While Odim has testified that this event did not take place, the evidence suggests clearly that it did. It is difficult in fact, to determine why Odim continued to maintain, even while testifying, that the event did not occur, despite the overwhelming evidence to the contrary.

In his letter to Collison, Odim also stated, "despite what was a relatively smooth repair issues with cannula site obstruction necessitating repair and revision prolonging the circulatory arrest and total pump time clearly had a bearing on this child's outcome." (Exhibit 8, page MAG 22) The evidence—particularly the length of the initial TCA and the inadvertent decannulation—indicates that this was not a smooth repair.

The evidence also suggests that Odim did not give the referring doctor a full and accurate account of what occurred in the OR before the death of Jesse Maguire.

What was the cause of death and was it preventable?

- Finding

Taylor, in his report, concluded as follows:

> The proximate cause of the death of this child was myocardial injury resulting from excessively long circulatory arrest and cardiopulmonary bypass times. A major factor leading to the prolonged times was thoracic aortic obstruction complicating the initial repair of the interrupted aortic arch. This was thought clinically due to an aortic cannula that was felt to be relatively large for the abnormally small vessel, then subsequently to a stenosing aortic suture line. Attempts to correct this obstruction led to disruption of the anastomotic site requiring further circulatory arrest and cardiopulmonary bypass. (Exhibit 336, page 11.1)

Based on all of the evidence, the conclusion drawn by Taylor seems to be the correct one. The evidence suggests Jesse died because his heart had undergone an excessively long surgical procedure, from which it could not recover. The length of the operation was increased, it would appear, by the surgeon's inexperience, a dislodged cannula and an anastomotic tear caused by attempts to reinsert the cannula. Therefore, the evidence suggests that this was a preventable death.

The length of time that Jesse underwent total cardiac arrest also probably meant that, even if he had survived the operation, he would have suffered severe brain damage.

The tragic events of this case not only heightened the tensions in the OR, but soon became the subject of some discussion with the heads of the various departments.

MEETING OF THE DEPARTMENT HEADS – NOVEMBER 28

On November 28, the day after Jesse Maguire died, Odim met with Blanchard, Craig and Postl. The meeting had been previously arranged.

Postl testified that, at this meeting, Odim spoke of the need to consolidate post-operative care and reduce the number of anaesthetists. Postl also testified that "the tone and content of discussion was almost precisely what was in the letter." (Evidence, page 35,516) As a result, Postl began to wonder if it might be impossible to resolve all of the team issues. He also was surprised by some of the items included in Odim's proposed mission statement. The most surprising was the concept of performing heart transplants in Winnipeg. At the meeting there was discussion of whether there should be an external review or if it would be more appropriate to await Lindsay's arrival.

In late November or early to mid-December, Postl in fact met with Lindsay. They spoke about the Pediatric Cardiac Surgery Program. According to Postl, Lindsay indicated that he was open to reviewing the program. The need for an external review became more apparent to Postl after his meeting with Lindsay, as he became aware of the events that had occurred in the OR during the operation on Jesse Maguire.

THE IMPACT OF THE MAGUIRE CASE

The Maguire case had considerable impact on the persons who participated in the operation. Within days, several of the participants took their concerns to Giddins, Craig and Postl.

Ward said that, while he had approved of the Wiseman Committee decision to proceed to offer a full service, including high-risk cases, he began to have reservations following the Maguire case. "I wondered at that time, which was towards early December, then I kind of wondered about the high risk surgery at that point in time." (Evidence of Dr. Ward, page 108) He wondered if there should not have been a different surgical approach in this case. He was also concerned that Odim and Swartz had given him differing accounts of what had happened to the cannula during the operation. Ward said that he communicated his concerns to Giddins. In his testimony, Giddins said he asked Ward to speak with Odim and straighten out this conflict. According to Giddins, Ward never reported back to him on the issue and he did not investigate the matter himself. Shortly afterwards, Ward went on vacation and when he returned, the program had been shut down.

Following Jesse Maguire's death, Swartz said, she was shattered and devastated. Within 24 hours, she spoke to both McNeill and Craig and expressed her concerns with the operation.

Youngson stayed off work the day after Jesse's death. She returned to work on November 29 and went to see Isobel Boyle, outlining her concerns with the program. Boyle arranged for Youngson and Hinam to meet with Postl. According to Youngson, Postl gave them a sympathetic hearing, but then told them what Youngson had been told by others. This was that Duncan had experienced similar problems in his first year and that it could be expected that not all high-risk cases would be successful. Youngson outlined once more her concerns about surgical technique and bleeding.

Boyle gave this description of the meeting with Postl.

> So the three of us met with him the following day and Carol and Irene described the OR situation with him. And they—and when I would talk to them, you know, in terms of what can we do, I mean, they were so dedicated to going back for the children and the families, and that they thought if we don't go in there, what are they going to do?
>
> Brian also asked them, he asked them if they wanted the program stopped; and it wasn't the program they wanted stopped, they wanted the incidences to stop. And he also asked them, what would make it—what did they think might make it better? And they said that certainly the cases that Dr. Hamilton had been involved in seemed to go better. (Evidence, page 32,709)

Postl recalled that the nurses made it clear that problems they had flagged early in the year were still present. Postl said:

> I was struck by the intensity of their feeling about this situation. I was struck that they truly believed that these were very significant issues. And I was struck that they seemed very uncomfortable and, in fact, at least one of them was tearful during this description. (Evidence, page 35,544)

Casiro testified that he had expected Jesse Maguire to survive surgery. During the course of the Maguire operation, Casiro had spoken with Swartz, who had told him about the inadvertent removal of the cannula. Casiro subsequently spoke with Odim and was troubled by the fact that his version of the story did not mention the dislodging of the cannula and the problems encountered while reinserting it.

Casiro did not keep his troubled thoughts to himself. He spoke to Seshia about the conflicting versions and his own lack of understanding of what went wrong. He said he faced an ethical dilemma.

> Well, it is sort of being torn between the loyalty or allegiance to the institution and the program, and to the patient and the family. And, you know, what is in the best interests of the patient, which is ultimately what we are advocating for.
>
> And in my own mind, I start to question, asking, well, if I have this level of concerns, should I share this with the parents the next time I have a complex case that needs to have surgery? (Evidence, page 37,989)

Casiro indicated that he also spoke with Postl on December 2. (Postl placed this meeting three weeks later, on December 21.) He told Postl about his uncertainties with the program and said that he thought the issues regarding these cases (ID and Maguire) needed clarifying. He also told him about his ethical concerns.

According to Casiro, Postl told him he would speak to Blanchard. He also told him that he was seeking to have Lindsay review the program. Casiro said that Postl was jolted when he told him he was thinking of telling patients about his concerns.

Joan Borton was also becoming increasingly distraught over the outcomes. During this period Giddins encountered her at a time when she was in tears over events in the program. He told her that many people were worried about her. This shocked her. He then asked, "Are you with us?" to which she answered no (Evidence, page 18,243).

> And I said to him, you think I should leave. And he said, well, yes. I said, well, I have been trying to leave. I have taken steps. Isobel has been involved. You know, it's just that I can't just do anything as a nurse. And he said, well, no, of course, you can't just do anything, but there are some things that you can do. And I went, well, why don't—what about if we have a meeting with Isobel. I will call Isobel and the three of us will sit down and really talk about what this is all about. And he agreed. (Evidence, pages 18,243–18,244)

The three met and a decision was made to find a term position for Borton outside the Variety Children's Heart Centre.

Hinam testified that by this point, she believed that no one who knew anything about the program would have allowed his or her own child to be operated on by this team. Hinam testified that she asked Kesselman if he would allow any of his children to undergo an operation in the Winnipeg program. She said at first he said he would not because he was personally acquainted with everyone involved. She asked Kesselman if that would still be his view if the Winnipeg surgeon were the best in the country. According to her testimony, Kesselman said that on that basis, he would allow his child to undergo cardiac surgery in Winnipeg. She said that other people involved in the program had said to her that they would not allow their children to be operated upon in Winnipeg.

> The Wiseman committee didn't seem to have accomplished anything. And I just, I guess it was just like you felt like you were batting your head against a wall. (Evidence, pages 11,555–11,556)

In his testimony, Kesselman gave the following account of the conversation:

> I recall that she kept asking me this, and I kept saying the things that I said to her, well, you know, that I think it's probably different for me, the inference being that if my child needed brain surgery or something, I might want to go somewhere else. And she kept on. I actually got quite irritated, and I just kind of said that to kind of end it, because she had asked me many, many times.
>
> I think that probably wasn't the best thing to say. I think that was probably somewhat ill considered on my part. If this, you know, is to be taken as my views, other than really just a personal conversation. (Evidence, page 34,142)

Hinam testified that she went to see Boyle, who took her to see Postl. She said that she went to see Postl twice, once with Youngson.

> I told him about this informal survey that I had taken, and how angry I was that we were continuing when people that didn't know any better, with only people that didn't know any better's kids. Because nobody that I talked to that day would ever let their children be done here. (Evidence, page 11,557)

In the wake of these discussions, Postl called Blanchard. He spoke with him about the concerns that the nurses and Casiro had expressed. One of the ideas that Postl and the nurses discussed was to have Hamilton present when Odim operated. Postl was impressed that the nurses had such confidence in Hamilton. Postl and Blanchard agreed that, for future cases, Hamilton would assist Odim. However, Postl could not recall if they had specified the kinds of cases at which this assistance would be provided. Postl thought that this would help to alleviate the concerns of those who had spoken with him, while he waited for Lindsay to arrive and review the program.

The dilemma that Hinam put to Kesselman was not always hypothetical. Donna Feser testified that a friend phoned her that autumn to ask about the program because a relative had a child scheduled to undergo surgery at the HSC. She asked Feser if she would allow this to happen if this were her child. Feser told her no.

> I felt a moral obligation. And when I say I put myself in her position, I also was thinking, I was thinking of the child, I was thinking of the parents, I was thinking of the people that I had already seen go through this process, and seen the suffering, seeing the suffering of the Goyal family. (Evidence, page 30,042)

One cannot take issue with Feser's actions, which were taken on the basis of what she viewed as a moral imperative. However, when coupled with Borton and Hinam's testimony, it gives rise to two observations.

The first is that it would appear that people who had access to inside information were being warned away from the program, although these warnings were not being given or condoned by the program's leadership. Secondly, one is left with the sense that, just as Hinam had predicted in the spring, the program would have been subjected to a much more intensive review much earlier if the parents of the children who died had enjoyed greater socio-economic status and greater access to the workings of the hospital and the medical system.

THE CASE OF JR – DECEMBER 2

JR was born on November 21, 1994. At birth, he was diagnosed with an atrial septal defect, a ventricular septal defect and tricuspid atresia. He also suffered from a clotting disorder that was not diagnosed until after his first operation on December 2, 1994. He was transferred to the HSC on November 25. Following his transfer to the HSC, he underwent a balloon atrial septostomy and two separate operations. The septostomy took place on November 25. The first operation took place on December 2 and the second on December 8. After surgery, JR was transferred to the NICU, with an open chest. His chest was closed on December 14. He remained in the HSC for a further six months, because of coagulation problems and his ongoing cardiopulmonary distress. In the spring of 1995 JR was transferred to Saskatoon, where he underwent additional cardiac surgery. He was then returned to the Winnipeg PICU for further care.

On December 2, 1994, JR's oxygen saturation had fallen dramatically. It was felt that if a Blalock-Taussig shunt was not inserted, JR could have a cardiac arrest on the ward. Odim was consulted, and the child was scheduled for emergency heart surgery in the Children's Hospital.

The placement of a Blalock-Taussig shunt was a closed-heart procedure that did not require that the child be put on CPB. However JR was a neonate whose condition was fragile. Obviously there was concern about the state of his health and about his ability to withstand the operation.

More important, however, was the concern that, while the placement of a Blalock-Taussig shunt was a closed procedure, there was always an inherent risk that the shunt would not do what was expected of it. For any one of a number of reasons, the chances of having the operation suddenly become one where open-heart procedures would be required, while perhaps remote, were real. There was a clear possibility that the team might require the use of the CPB machine.

As a result of the speed at which the case proceeded, however, the operation could not take place in OR Theatre 2. This was the usual pediatric cardiac operating room, but it was being used for another operation. Instead, JR underwent his operation in OR Theatre 1. Both Wong and McGilton were worried about proceeding with the operation, since the OR they would be using lacked equipment that was available only in

OR Theatre 2. McGilton and Wong were particularly concerned because, if bypass became necessary, the perfusion equipment that would be needed could not fit into OR Theatre 1.

Wong said that, once he became aware of the emergency nature of the case, he agreed to go ahead with the procedure. While Wong was the anaesthetist initially, Ullyot replaced him later in the procedure. There was nothing unusual in this, since the operation was a closed heart, as opposed to an open-heart, procedure. Ullyot said that she had had considerable past experience with the placement of B-T shunts, although this was the first time that she had worked with Odim.

At approximately 1645 hours, Odim announced that the shunt was open. It was expected that this would cause a decrease in blood pressure and an increase in oxygen saturation. However, this did not happen. At the time, Odim said that he could feel blood flowing through the shunt. Eventually the blood pressure and the oxygen saturation reached acceptable levels, and at 1730 hours Odim began to close the chest. When he finished closing the chest at 1800 hours, both the blood pressure and the oxygen saturation fell. At Ullyot's suggestion, Odim loosened the sutures and opened the chest. However, JR's oxygen saturation and blood pressure did not improve.

Odim examined the shunt and found that it had clotted, even though he had treated JR with heparin. After attempting, without success, to unblock the shunt and after having consulted with Giddins by telephone, Odim decided to construct a central shunt. (This central shunt would connect the aorta to the main pulmonary artery.) Once this shunt was in place, however, the pressure and oxygen saturation problems were still not resolved.

Odim considered going on bypass and putting in a third shunt. In preparation for this, a call was put out for a perfusionist. Todd Koga, who was on call, was paged and rushed from home to the Children's Hospital. By the time he arrived, Odim had decided not to put in a third shunt. Instead he found he could maintain JR's oxygen saturation at an acceptable level by treating JR with inotropic medication. JR was taken to the NICU with his chest open.

Following that operation, a heart catheterization was undertaken. According to Reimer, who gave the anaesthetic for the catheterization, JR was unstable and suffered two cardiac arrests during that procedure.

In the NICU, JR's shunt once more became clotted. Tests were conducted and the results indicated that JR had a blood condition that increased the tendency of his blood to clot. He was treated with anti-coagulants and a decision was made to put in a third, larger shunt. This operation took place on December 8.

At that time Odim placed a 4-millimetre shunt, larger than the 3.5-millimetre shunts he had used previously. He hoped that a larger shunt would be less likely to become blocked or occluded. As a result of the larger shunt and the anti-coagulation medication, JR's oxygen saturation improved. However, he was once more returned to the NICU with his chest open.

JR's previously undiagnosed blood condition contributed to the fact that his initial operation was very long, particularly for what was expected to be a relatively straightforward shunt procedure. The case was a matter of concern for the nursing staff in both the OR and in the NICU. McGilton testified that she had never seen a shunt become blocked in that manner, had never seen an eight-hour shunt operation and had never seen a shunt patient sent to the NICU with an open chest.

Armitage testified that the clotting of the shunt created a chaotic situation in the NICU. She said that Odim once again requested equipment that was not kept in the unit. She testified that many NICU nurses were becoming alarmed by the fact that so many of the cardiac patients were coming back from the OR in very serious condition. While it would appear that there were reasonable explanations for the problems that arose in this particular case, the atmosphere had become so tense and suspicious in the hospital about the program that even explainable events were given only negative interpretations.

BLANCHARD'S MEETING WITH UNRUH AND ODIM – DECEMBER 5

On December 5, 1994, after Postl had spoken with him, Blanchard telephoned Unruh. The call was to inform Unruh that, despite the efforts of the Wiseman Committee, there were still ongoing reports of problems in pediatric cardiac surgery. Blanchard said that it would be useful to involve Hamilton in the team to a greater extent. He asked Unruh to attend a meeting later that day, at which Blanchard would inform Odim of this decision. He wanted Unruh to be present at the meeting to provide support to Odim, who he thought would be demoralized by the decision.

Blanchard testified that while he thought that Odim needed help, Odim did not appear to feel he needed assistance.

> And perhaps he hadn't thought about it, you know, and when you are in the middle of a swamp, you know, you are so busy with the alligators you may not think of everything, but he didn't seem to—what shall I say—I got the feeling or maybe he told me that he hadn't thought about that. (Evidence, page 36,638)

Odim himself testified that Blanchard felt having Hamilton in the OR was a means of having someone there who could see things from a surgical perspective and verify Odim's account of how the operations were proceeding.

On the day after this meeting, Blanchard sent Postl the following memorandum:

> I met with Jonah Odim and Helmut Unruh on December 5th. It was agreed that Dr. Andrew Hamilton will assist Dr. Odim with all neonatal and all other high-risk cardiac operations. (Exhibit 19, Document 268)

Blanchard copied Odim and Hamilton with this memorandum, while Postl sent a copy of the memorandum to Boyle.

While there can be little doubt of the meaning of this memorandum, Odim testified that the memorandum did not reflect the agreement that had been reached at the December 5 meeting. In particular, he said, he understood that he was to have Hamilton's assistance for only open-heart neonatal cases and not for all neonatal cases.

Blanchard was asked what the memorandum meant by the phrase "all neonatal."

> Well, I meant neonatal, I believe that is patients in the first month of life.
>
> *Q* Certainly. I guess the question that's come up is, did you mean, did you mean all neonatal cases, including closed and open, which would—or what did you mean in that regard?
>
> *A* Okay. I can't remember what I meant. I should have been more specific, but, I mean, the three of us generated this thought. The way it stands it would mean all neonatal, but probably what we had in mind was all open neonatal cases. (Evidence, page 36,639)

According to Unruh, at the meeting Blanchard informed Odim that the only way the program could be salvaged at that point was to have Hamilton present for "all of the major cases." (Evidence, page 35,210)

The difference between Odim's recollection of the agreement and the wording in the memorandum is particularly significant in light of Blanchard's response when he was asked to explain the purpose of the December 6 memorandum to Postl.

> I think the memo was written for several reasons. One is to underscore with Jonah that we expect this, it isn't an option. And the other was to inform everyone else – it wasn't a problem for Dr. Hamilton, we knew that, just to inform everyone else that they would expect this to happen. And I think it would also serve to reassure Dr. Postl, who had told me that he had been informed that things went well, you know, in these complex cases when Dr. Hamilton was present. (Evidence, page 36,641)

It is difficult to square the clarity of the memorandum with Odim's and Blanchard's evidence. Postl initiated the request to have Hamilton present because of concerns that had been presented to him about surgical outcomes. The memorandum did indeed provide him and the nursing staff with a measure of assurance.

However, if Blanchard and Odim had not agreed to what the memorandum said, then it would appear that it was a false assurance. Either Blanchard worded the memorandum in a manner that did not reflect the understanding between Odim and himself, or—as the evidence in the later Petkau case suggests—Odim chose to disregard the memorandum. Blanchard was not clear in his testimony as to the nature of the agreement. It would have been appropriate if Odim or Blanchard had corrected the impression that was left by the memorandum. In light of their failure to do that, they ought to have abided by the written memorandum.

Giddins testified that he did not receive a copy of the December 6 memorandum; nor was he told of its specific contents. He did say that Postl informed him that formal arrangements had been made to have Hamilton assist at operations.

THE CASE OF KQ – DECEMBER 7

On December 7, Odim, with Hamilton as his assistant, operated on KQ, a six-week-old child with total anomalous pulmonary venous connection (TAPVC) and a large ASD. This high-risk operation went well. She was discharged on December 22, 1994.

McGilton, who was a circulating nurse for this procedure, said that Hamilton played a leadership role in the operation. Reimer, however, was less certain if Hamilton's presence was significant, since Odim performed the bulk of the procedure himself.

THE WISEMAN COMMITTEE MEETING OF DECEMBER 7

The committee met again on December 7, for the first time since October 17. In the intervening period, the deaths of Jesse Maguire and Ashton Feakes had occurred. The main topic at the meeting was the proposed centralization of post-operative care. It appeared that the NICU nurses were now more amenable to the single-unit proposal, although it was recognized that the PICU nurses would require additional training in caring for neonatal patients.

However, at this meeting Kesselman raised concerns about the impact that the consolidation would have on the resources of the PICU. Nor was it possible for Cardiology to provide any additional support for post-operative care. McNeill moved that the post-operative care process remain unchanged for the moment, since existing resources would not support the single-unit approach. While it was recognized that this decision was necessary, Odim's disappointment was recorded in the minutes.

The members of the committee were not informed of Blanchard's directive of December 6; nor, in keeping with Blanchard's instructions, were they informed of Odim's letter of September 25, despite the fact that Wiseman had been given a copy of it on October 28. Although Wiseman may not have been aware of the December 6 directive, certainly by that time Odim had seen the directive or was aware of its contents from the meeting he had had the day before with Blanchard. The information was a matter of considerable interest and importance to committee members and should have been shared with them.

At the meeting's end, Wiseman reported that, in view of recent events, the surgical procedures carried out in September, October and November would be reviewed. The matter was not put to a vote of the committee, and apparently came directly from Wiseman. This could have done to meet Seshia's expression of concern that the program outcomes were still problematic. However, the recent events to which Wiseman referred were undoubtedly the cases of Ashton Feakes, JR, ID and Jesse Maguire. Wiseman may also have been influenced by Odim's letter of September 25. He reported that it was also expected that when Lindsay took up his duties, he would provide guidance for a further review of the program. The committee's reviews were to be performed at a meeting set for December 16. That meeting was never held.

ULLYOT MEETS WITH POSTL – DECEMBER 9

On December 9, Ullyot met with Postl to discuss a range of issues, including the Pediatric Cardiac Surgery Program. She told Postl that the four anaesthetists were not happy with the program and still had concerns.

Postl spoke with his vice-president, Helen Wright, during this period. According to her testimony, Postl sought her advice on how he might close down the Pediatric Cardiac Surgery Program if he became convinced that such action was necessary. In recalling that conversation, Wright said Postl did not discuss specific cases with her, but he indicated that there were growing concerns with the program. She said Postl indicated that he was examining options if a worst-case scenario arose. She told him that he could go to the Medical Advisory Committee (MAC) and ask that the program be stopped or that Odim's privileges be suspended or revoked. She also advised him to make sure that he had a firm understanding of the statistical results of the program. She said that if the MAC rejected this recommendation, he could then appeal to the President and the Board.

In December, Wright also heard from Boyle at least twice about nursing concerns with Odim's surgical competence. Wright said this was after her discussion with Postl. She indicated that, in previous discussions with Boyle, she had thought that the nurses' concerns related more to communications and interpersonal relations. Wright believed that Postl was taking steps to address these concerns. Within a short time, he had.

THE CASE OF ERIN PETKAU

ISSUES

Erin Petkau died on the morning of December 21, 1994, after undergoing surgery to insert a Blalock-Taussig shunt on December 20.

The issues that this case gives rise to are:

- Were Erin's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should the ventilation intra-operatively have been different?
- Was the Blalock-Taussig shunt too small?
- What led to the shunt failures?
- Should Dr. Andrew Hamilton have assisted in this operation?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Erin Petkau was born at Morden District General Hospital on December 17, 1994, at 0706 hours. The child of Walter and Barbara Petkau, she was born at 41 weeks gestation and weighed only 2,610 grams.

On December 18, after Erin had cyanotic spells and a heart murmur was detected, she was transferred to the HSC. On admission to the HSC at 2007 hours, her colour was pink and her oxygen saturation was good. She was also noted to have good femoral pulses and peripheral perfusion.

Tests conducted on December 18 and 19 identified:

- Tetralogy of Fallot with a marked aortic override above a large ventricular septal defect and right ventricular hypertrophy
- either an atrial septal defect or a patent foramen ovale
- severe pulmonary valve stenosis
- small pulmonary arteries
- a patent ductus arteriosus.

Erin's aorta was positioned over the top of the ventricular septum (and thus termed an 'overriding aorta'), rather than being attached to the left ventricle. She had a large hole in the septal wall separating the ventricles. In addition, her ductus arteriosus was open and she had either an atrial septal defect or a patent foramen ovale, linking her atrial chambers.

Erin was treated with antibiotics for a possible infection. Dr. Soni saw her at 0400 hours and performed an echocardiogram. Soni assessed Erin as a pink Tetralogy of Fallot and recommended treatment with prostaglandin if there was a decrease in oxygen saturation. Giddins concurred with this assessment and indicated that surgery to insert a shunt was required. According to Barbara Petkau, Soni told the family that Erin would likely need surgery within one or two weeks.

THE DECISION TO OPERATE AND CONSENT

On the morning of December 19, Giddins conducted a second echocardiogram. He concluded that, while Erin's oxygen saturation was satisfactory, she would be in trouble once her ductus arteriosus closed. For this reason, he concluded that a shunt was required.

Erin was treated with prostaglandin to keep her ductus arteriosus open. Giddins testified that this was done in response to her history and heart condition and not as a response to any decline in her condition.

At 1610 hours on December 19, Erin became very cyanotic during feeding and stopped breathing for about 30 seconds. She was ventilated by hand with oxygen, and secretions were suctioned from her lungs. She started to breathe again and her colour remained pink until 1620 hours, when she stopped breathing again. After three attempts, an endotracheal tube was inserted and a moderate amount of thick secretions were suctioned out. A chest X-ray was interpreted as being normal.

Giddins testified that, on December 19, he discussed the need for surgery within the next one to two days with Erin's parents. He recalled explaining the operation as a relatively simple procedure, in which a tube would be placed between two blood vessels. He testified that he did not recommend any alternatives because he did not believe there were any; nor did he discuss having the operation undertaken at a different centre. In his testimony, Giddins said that he thought that surgery had a five to ten per cent risk of mortality. He indicated that he did not discuss risk with the parents. Because Odim was not available for a consultation that weekend, no date was set for surgery.

When the Petkaus went to visit Erin on Monday, December 20, they were told that they could not see her because she was being prepared for surgery. This surprised them, since they had yet to meet the surgeon. They had thought that surgery would not take place for several days. They said they were told that while Odim had previously been unavailable, he now was available and ready to operate. Barbara Petkau testified:

> We just thought at the time, well, like, better sooner than later. If it has to be done, get it done and over with, and we can be on our way. They more or less assured us that we would be out of there by New Years. (Evidence, page 2,523)

On December 20 at noon, Odim assessed Erin and determined that she needed a Blalock-Taussig shunt to provide her with a stable source of blood flow to her lungs. He then spoke with the family. In his testimony, he said:

> I don't remember the exact wording of the conversation except to discuss that the child needed to have a shunt for pulmonary blood flow, talked about the anatomy of the child and talked about what happens next after a shunt in terms of the child would need another operation to fix the heart, talked about the problems that you can get with shunts, including redoing them or the shunt blocking and that essentially was sort of the gist of my conversation. I don't remember the wording, the exact wording. (Evidence, page 26,238)

He also spoke to Erin's parents about risk. He testified that:

> I essentially told them that there are risks from a shunting procedure of bleeding, of clotting, having to do the shunt again, that there were risks of death and I told them that 8 to 12 or 8 to 10, I don't recall the exact ball park, of patients would have problems with a shunt including death. (Evidence, page 26,240)

He testified that he did not believe he had indicated what per cent of that eight to twelve per cent were at risk of dying.

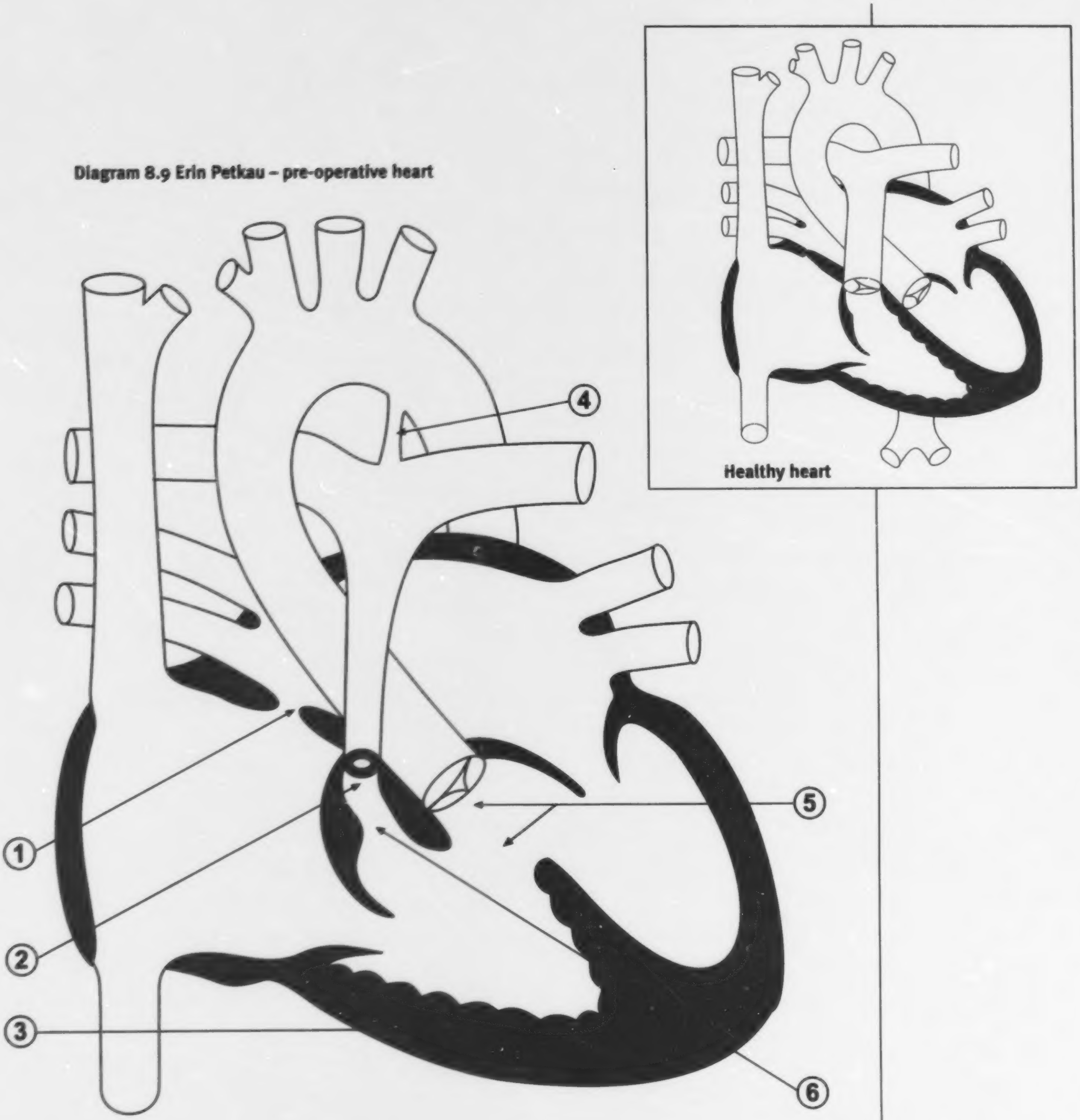


Diagram 8.9 Erin Petkau – pre-operative heart

1 – Atrial septal defect
2 – Severe pulmonary valve stenosis
3 – Right ventricular hypertrophy
4 – Patent ductus arteriosus
5 – Ventricular septal defect with overriding aorta
6 – Right ventricular outflow tract obstruction

Barbara Petkau testified that Odim had drawn them a picture of the heart and indicated its lesions. Furthermore, he told them that it was a very low-risk operation. Barbara Petkau also testified that, as a result of her discussions over the weekend with Soni and Savani, she was left with the impression that Odim was one of the best available surgeons.

PRE-OPERATIVE STATUS

During the night of December 20, Erin's extremities were very cool, and she was placed under a radiant heater. She was very irritable and tremulous but settled with sedation.

In his report, Hudson raised a potentially serious point. He wrote that:

> A coagulopathy was present before surgery. I was not able to locate any notations in the chart that indicated that anyone involved in the care of this patient was aware of these results. Intraoperative and postoperative bleeding were major problems that likely contributed to the death of this patient. ***The failure to diagnose and treat this coagulopathy before surgery are major deficiencies in the management of this patient.*** (Italics and bolding in original) (Exhibit 307, page 12.14)

Hudson subsequently revised this conclusion. Documentation was presented to him indicating that there had been a pre-operative administration of Vitamin K, the treatment that he believed had not been provided. Secondly, he agreed that the lack of bleeding in the early stages of the operation indicated that Erin did not have a coagulopathy pre-operatively:

> I would agree with Dr. McNeill's conclusion that those results then, in a neonate and in the context of having been given vitamin K, are at best mildly abnormal. (Evidence, page 40,049)

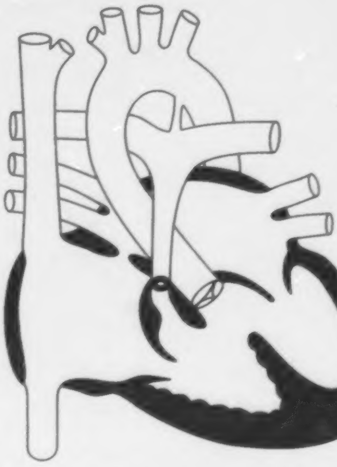
With the resolution of this issue, it can be concluded that the diagnosis, pre-operative care and surgical plan were appropriate in this case.

THE OPERATION – DECEMBER 20

Starting at 1240 hours on Tuesday, December 20, Erin underwent what was expected to be the insertion of a Blalock-Taussig shunt. It would become necessary during the procedure for Odim to ligate the ductus arteriosus and to insert a central shunt. As a result, the operation became very lengthy. Erin died on the morning after surgery in the NICU.

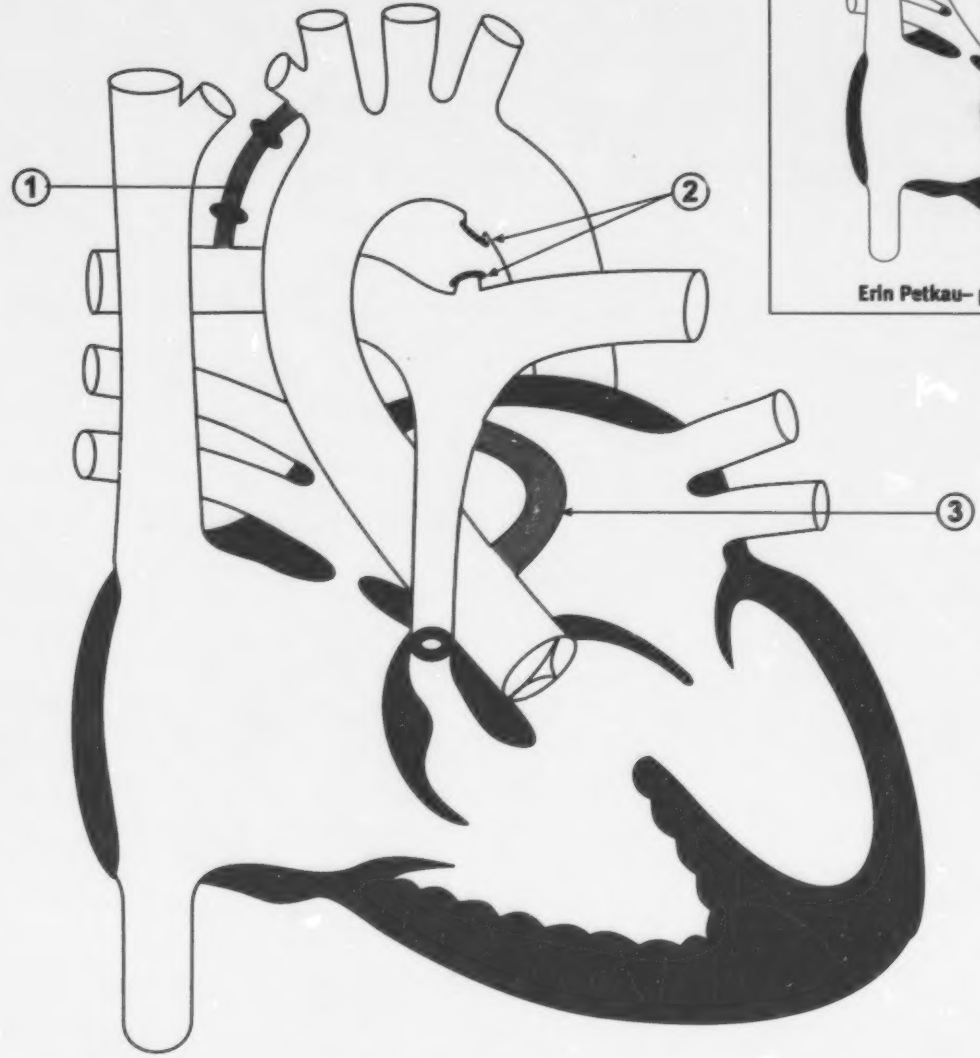
To conform with the written instruction from Blanchard as set out in the memorandum of December 6, 1994, Odim was required to call Hamilton to have him assist with this procedure. Odim testified that he did not because "that wasn't my understanding of my conversation with Dr. Blanchard." (Evidence, page 26,256)

Odim stated that he called Hancock because she had been assisting him throughout the year. "I could have called anyone I wanted who might be available to assist me." (Evidence, page 26,257) He further testified that he understood that he was to have Hamilton's assistance at only open-heart neonatal procedures, not all neonatal procedures. The evidence suggests that on that point Odim was not correct. In failing to have Hamilton present for this procedure, Odim was acting outside the written directive that he had received.



Erin Petkau– pre-operative heart

Diagram 8.10 Erin Petkau – post-operative heart



1 – Modified Blalock-Taussig Shunt, clipped
2 – Ligation and division of ductus arteriosus
3 – Central shunt

The operating team is set out in the accompanying chart.

TABLE 8.9: Persons involved in the operation on Erin Petkau, December 20, 1994

OR team member	*Persons involved*
Surgeon	J. Odim
Surgical assistant	B.J. Hancock
Anaesthetists	A. McNeill, N. Svorkdal (resident)
Scrub nurses	H. Skomorowski, C. McGilton, A. Glenday
Circulating nurses	C. Youngson, K. Rodgers, K. Cox, and H. Skomorowski
Perfusionists	T. Koga, C. McCudden

TABLE: 8.10 Length of phases of the operation on Erin Petkau, December 20, 1994

Phase of the operation	*Time taken*
Induction	1 hour 15 minutes
Bypass	1 hour 39 minutes
Total surgical time	10 hours
Total operating-room time	11 hours 50 minutes

During induction, Odim performed a cut-down for the insertion of an arterial line. This procedure involved surgically exposing an artery in the wrist and then inserting a monitoring line.

According to Cornel and Hudson, Erin had a metabolic acidosis at the start of her operation that continued throughout surgery.

The initial chest incision was made at 1355 hours. In the operation, Odim used a 3.5-millimetre Gortex tube graft to connect the subclavian artery to the right pulmonary artery. When the shunt was opened at approximately 1510 hours, the systemic blood pressure fell. Odim testified that he became concerned that this was a sign that too much blood was being shunted to the lungs, as opposed to the body. (The systemic pressure falls when there is not sufficient blood flow to the body.) Erin became increasingly acidotic as a result. Odim believed that his only options were to make the shunt smaller or close the ductus arteriosus, thereby reducing blood flow to the lungs. As a first step to doing this, he stopped the flow of prostaglandin, in hopes that the ductus arteriosus would close on its own. He then manually pinched the ductus arteriosus and the pressures went up. After speaking with Giddins by phone, Odim decided that he would ligate the ductus arteriosus. He hoped that this would reduce the blood flow to the lungs and improve systemic blood pressure. At the same time, McNeill was transfusing additional fluids and treating Erin with dopamine in an effort to increase her blood pressure.

Throughout this portion of the operation, McNeill ventilated Erin with 100 per cent oxygen. In his testimony, Odim said that it might have been appropriate to reduce the amount of oxygen with which Erin was being ventilated after the shunt was inserted. He testified that oxygen would have dilated the vessels leading to the lungs, thus increasing pulmonary blood flow at a time when he wanted it decreased. He testified that he was not aware that Erin was being given 100 per cent oxygen at that time and he did not inquire about a change in oxygenation.

The PDA was ligated, with some improvement. However, each time Odim attempted to close Erin's chest, her blood pressure dropped. Odim testified that at one point the pressure was so low that there was no pulmonary blood flow through the shunt. The decline in blood pressure and blood flow created the possibility of clotting in the shunt. There was also less blood going to the coronary arteries, which perfuse the heart muscle itself, threatening to weaken the heart. McNeill began treating Erin with epinephrine, a stronger inotrope.

Odim reopened Erin's chest at 1610 hours and examined the Blalock-Taussig shunt. He found the shunt blocked with clotted blood. He was able to momentarily open the shunt by passing a catheter though it, but the shunt soon closed again. This took place at approximately 1700 hours.

Blockage of the shunt created a new problem, since at this point, with the ductus arteriosus closed, the shunt was the only source of blood flow into Erin's lungs. To reverse this, Odim released the ligature on the ductus arteriosus. An infusion of prostaglandin was restarted. However Erin's pressures remained low and the ductus arteriosus failed to reopen.

Odim testified that, at that point, he was not able to determine the cause of the problem.

> I was wondering whether the pulmonary arteries were too small in this child, and we were having problems with the outflow bed. Because I was perplexed, I had never been in a situation where I was just so over shunted with a 3.5 millimetre shunt.
>
> *Q:* And what happened then?
>
> *A:* When the shunt occluded, we were still faced with a tremendous acidemia and requirements for inotropes. And Erin needed, you know, another shunt, needed pulmonary blood flow, because now we had no pulmonary blood flow. (Evidence, page 26,292)

From 1700 hours onwards, there were periods when Erin's blood pressure and oxygen saturation were acceptable, but these periods did not last for more than fifteen minutes. By 1840 hours, her blood pressure and oxygen saturation had fallen again and were not responding to treatment. During this period, she suffered a reduction in oxygen supply to her tissues (hypoxemia) that was, at times, life-threatening.

Odim concluded that creation of a second shunt was necessary. To do this, he would have to use bypass, so that he could gain access to the small blood vessels that were to be connected by a central shunt.

Barbara Petkau testified that, at approximately 1830 hours, Savani informed the family that the initial shunt procedure had not gone well. As a result, Erin would be put on bypass and a second shunt inserted.

The anaesthetists packed Erin's head in ice at approximately 1900 hours, when the perfusionists were called. The team went on bypass at 1927 hours. The move to go on bypass was delayed when it was discovered that the single venous cannula that was being used was too small to supply an appropriate level of blood flow from Erin to the bypass machine. Koga had recommended a smaller-size cannula, since he was under the impression that Odim would be using two cannulas for the venous return, whereas Odim intended to use only one cannula. Although the problem lasted only a few minutes, it was further evidence of ongoing communication problems between team members.

Following the operation, team members also had differing accounts of how the original cannulation problem arose. McNeill felt that Odim should have recognized that the cannula was too small before he inserted it. Odim said that Koga had simply failed to provide him with the appropriate cannula. However it is obvious that Odim failed to notice that he had been given the wrong-size cannula for what he intended.

By the time bypass was initiated, two and a half hours had passed from the time that the shunt had clotted. Once bypass was initiated, Odim constructed a four millimetre central shunt. He also clipped the original B-T shunt to ensure that it did not reopen and create excessive pulmonary blood flow once again. The team then attempted to wean Erica from bypass, which had lasted for 109 minutes. High doses of inotropes were required to allow separation from bypass, which took place at 2106 hours.

When Erin first came off bypass, her blood pressure was low and was treated with dopamine and epinephrine. She required this treatment to maintain her blood pressure at acceptable levels while in the OR.

Erin's condition was so serious while she was coming off pump that the OR team called Giddins and asked him to come down to the HSC. The team also requested that a chaplain be called to the hospital. NICU nurse Armitage called the chaplain and took him to see the Petkaus. The parents were told that Erin's situation looked serious. Shortly afterwards, Giddins arrived at the HSC. By that point Erin had been successfully weaned from bypass. Giddins communicated this news to Erin's parents and told them that things were looking well for Erin. Unfortunately, this was very shortly after Armitage and the chaplain had left the Petkaus with the impression that Erin's condition was bleak. The unfortunate timing of these two events was distressing for Erin's parents. This was particularly so since Giddins, quite unintentionally, had left them with what proved to be an overly optimistic picture of Erin's condition.

After Erin came off bypass, she suffered extensive bleeding. This was due to a number of causes, including the fact that she had been treated with heparin to prevent clotting. She also had some surgical bleeding from her chest wall at the site of the insertion of the right atrial catheter (a small pressure monitoring line) and at the site of the Blalock-Taussig shunt. In her testimony, McGilton said that it took approximately three hours to control the post-bypass bleeding. She said that Odim made several attempts to close Erin's chest. However, he had to abandon each one because the closure caused the blood pressure and oxygen saturation to fall and was accompanied by bleeding from the chest.

Giddins commented that the bleeding did not surprise him:

> The fact that it hadn't been bleeding during the case and the fact that it perhaps starts to leak a little bit, if there is a coagulopathy or tendency to bleed, doesn't particularly surprise me. You are not making it water proof. You are making a near water proof seal that depends on blood clotting to completely finish the job, but a little area that needed one extra suture doesn't strike me as being unusual. (Evidence, pages 4,547–4,548)

McNeill gave this description of the cause of the coagulopathy:

> I would attribute it to the effect of bypass on her coagulation status; and because of her size, she would have had a significant dilution of clotting factors and platelets because of the bypass situation, and whatever contribution there would be during bypass to platelet function deterioration, and then the massive transfusion post-operatively, which would further exacerbate the problem. (Evidence, page 13,614)

When the drapes were removed before Erin was taken to the NICU, it was discovered that she had been bleeding from the cut-down site in her wrist. In their evidence, McNeill and Odim differed in their accounts of the amount of bleeding that took place. McNeill viewed it as an extensive hemorrhage, while Odim said that it was insignificant. McNeill was asked about the significance of this bleeding.

> Well, the major significance of it was that this was of a covert bleeding site that we wouldn't have actually seen during the period of time when we were trying to volume resuscitate her. And whenever somebody is being transfused, you use their hemodynamic profile to determine whether you are adequately transfusing them. So, you know, it wasn't, we weren't actually aware that she was bleeding from her wrist, but we would have, we don't only use the bleeding that we see to replace blood loss. (Evidence, page 13,629)

While this blood loss would have been replaced by transfusion, it increased the volume of blood that needed to be transfused, thus raising the likelihood that Erin would develop a coagulopathy. There was no apparent explanation for the bleeding at the cut-down site. There was no evidence of bleeding when Erin was draped; nor does it appear that the line became dislodged during the operation.

After the bleeding sites had been identified and sutured, and resuscitative drugs and large amounts of blood products had been given, Erin was taken to the NICU with her chest incision covered with a silastic membrane.

In his report for this Inquest, Hudson wrote:

> There was massive intraoperative hemorrhage. The surgeon's and anesthetist's comments indicate that inadequate surgical hemostasis [this refers to the surgeon's control of bleeding] was an important cause of the bleeding. The patient received a total 800–900 ml of blood products during surgery, including albumin, PRBC [packed red blood cells], platelets, FFP [fresh frozen plasma] and cryoprecipate. This is over 3 times the blood volume of this patient (~90–100 ml/kg). (Exhibit 307, page 12.14)

In his testimony, Odim said he judged that the need to keep the shunt open was of greater significance than the need to bring the coagulopathy under full control.

By the time Erin left the OR, her heart had been subjected to considerable extremes in blood pressure and oxygenation. She had undergone an extremely lengthy operative procedure and suffered extensive bleeding. The evidence suggests that her system would have been very weakened as a result of this operation.

Erin arrived in the NICU at 0028 hours on December 21. Initially Odim considered her vital signs satisfactory. However, by 0200 hours, Erin had suffered a series of episodes in which her oxygen saturation fell significantly, and she was treated with massive doses of inotropes. She continued to have the same problems with bleeding, low oxygen (hypoxemia), metabolic acidosis and low calcium (hypocalcemia) that she had in the OR.

In response to the fall in her oxygen saturation, Erin's chest was reopened at 0225 hours. This was done in the NICU with the assistance of a nurse who was not scrubbed in and without the assistance of an anaesthetist. After discovering a clot blocking the central shunt, Odim flushed the shunt and passed a catheter through it.

Hudson questioned the propriety of opening the chest in the NICU without the presence of an operating-room nurse and an anaesthetist. He said that optimal management of the case would be "difficult or impossible" in their absence. (Exhibit 307, page 12.15)

The reopening of Erin's chest in the NICU was followed by a period of significant bleeding. In his testimony, Odim said that the underlying post-operative problem was Erin's declining cardiac output, caused by her weakened heart. This decline led to lower blood pressures and the blocking of the shunt. The problems were complicated by her small pulmonary arteries. The weakness of her heart muscle arose from the fact that, for the previous 18 to 20 hours, her heart been subjected to variations in blood pressure and oxygen saturation.

At 0500 hours, Erin's heart rate and blood pressure fell. These were signs of primary cardiac failure. Decreases in blood pressure led to a slowing of blood flow through the shunt and increased the chances of clotting. Giddins testified that as he understood it, Erin's problems were primarily with her heart rate and blood pressure and not with the shunt itself.

From 0500 hours onwards, Erin deteriorated rapidly, suffering a cardiac arrest on several occasions. For two hours, continuous efforts (including cardiac massage and flushing of the shunt) were made to resuscitate her. According to Hudson, Erin once again was given transfusions, which amounted to three times her blood volume, in response to what he termed a massive hemorrhage. (In his report, Hudson stated that Erin did not receive clotting factors post-operatively, but the post-operative record contradicted this statement.)

Erin's parents were summoned to her bedside. Barbara Petkau testified that she felt that it was only at this point that she was made aware that her daughter was near death. Erin died in her mother's arms at 0750 hours.

Armitage testified that she believed that some of Odim's comments about Erin's death were too technical and possibly insensitive to the parents. However, when giving her testimony, Barbara Petkau could not recall the comments.

AUTOPSY FINDINGS

De Nanassay performed the autopsy that had been ordered by the Medical Examiner on December 22 at 1530 hours. The report was released on February 20, 1995.

The cause of death recorded on the autopsy report form was:

> Immediate Cause of Death:
>
> Myocardial insufficiency post cardiac surgery for TOF.
>
> Antecedent Causes:
>
> Complete blockage of central shunt by coagulated blood. (Exhibit 9, page PET 9)

Erin's weight at autopsy was 900 grams more than her pre-operative weight. (She had weighed 2,610 grams at birth.) This was presumably due to fluid accumulation. Examination of the heart revealed extreme stenosis of the pulmonary valve, a ventricular septal defect and complete blockage of the central shunt (aorta to main pulmonary artery) by coagulated blood. De Nanassay noted that the pulmonary valve (as had been thought before surgery) was markedly narrowed and would have severely restricted outflow from the right ventricle.

Thus, the main source of blood flow to Erin's lungs was from the central shunt Odim had installed between the aorta and the main pulmonary artery. However, de Nanassay found that the central shunt was completely occluded by coagulated blood, thereby preventing any flow through it. De Nanassay concluded that, if the central shunt became blocked while Erin was still alive, any potential blood flow to her lungs would have been limited to what could pass through the extremely narrowed pulmonary valve. He also concluded that most of the non-oxygenated blood in the right ventricle was likely shunted into the left ventricle through the ventricular septal defect. The outcome would be minimal oxygenation of blood in the lungs, or central cyanosis. De Nanassay believed these findings explained the repeated episodes of oxygen desaturation and the repeated cardiac arrests, since Erin's heart would have been supplied with blood that was less than adequately oxygenated.

Concerning the microscopic examination of tissues, de Nanassay wrote:

> The two organ systems of major interest (the heart and lungs) are both essentially within normal limits. There is no evidence of ischemic changes in the myocardium. One tiny focus of subepicardial contraction band necrosis in the right ventricle more likely relates to traumatic causes in the course of surgery than ischemic damage. Both lungs were free of congestion or inflammatory changes. (Exhibit 9, page PET 12)

De Nanassay concluded:

> On the basis of the post-mortem examination the major pathological condition was that of a complete blockage of the central shunt. This factor would have to be coordinated with the clinical picture and analyzed in (the) context of other pertinent clinical information. The actual cause for coagulation of blood within the central shunt is not readily obvious from the morphological examination alone and clinical correlation might be helpful. (Exhibit 9, page PET 12)

Dr. W. Halliday, a neuropathologist, examined the brain and found recent hypoxic-ischemic damage.

Taylor reviewed the microscopic slides of the heart and lungs. He found the lung sections poorly expanded, with areas of recent onset bronchopneumonia. He found excessive numbers of amniotic fluid cells that Erin had inhaled or aspirated. He also found clumps of platelets and fibrin thrombi (which help to form blood clots) in both Erin's lungs and brain. These clumps were more prominent than those usually found in children who died shortly after undergoing bypass (Exhibit 336, page 12.3).

Taylor concluded:

> Abnormal coagulation, both thrombosis and bleeding, was a significant factor in the death of this child. ... However, the coagulopathy appears confined to the surgical field, with no evidence of major bleeding or thrombosis in other organ systems. (Exhibit 336, page 12.1)

Taylor found mild to moderate myocardial contraction band necrosis and ischemic damage to the muscle of both ventricles. (Exhibit 336, page 12.5)

In commenting on the autopsy specimen, Cornel and Duncan wrote:

> The aortic end of the surgical graft appears very small. [This refers to the second shunt.] Clot material in the shunt may have occurred either post-mortem or prior to death. The anatomy was poor with very small pulmonary arteries – we suspect there was poor run-off from the shunt. (Exhibit 354, page 15)

FINDINGS

As noted at the outset, this case gave rise to the following questions:

- Were Erin's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should the ventilation intra-operatively have been different?

- Was the Blalock-Taussig shunt too small?
- What led to the shunt failures?
- Should Dr. Andrew Hamilton have assisted in this operation?
- What was the cause of death and was it preventable?

Were Erin's parents provided with sufficient information to allow them to give informed consent to the procedure?

■ Finding

The family seems to have been fully informed as to the risks associated with the particular procedure that Erin was to undergo. However, they were not informed of the program's recent history, including the summer shutdown and the intention to have the program reviewed by an external examiner. They were entitled to know this information, before giving their consent. This evidence tends to suggest that Erin's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Should the ventilation intra-operatively have been different?

Odim testified that he thought that, in providing 100 per cent oxygen after the B-T shunt was opened, McNeill had violated a basic tenet of the ventilation of neonates. He testified that, if the level of oxygen given to Erin had been reduced, her oxygen saturation would have decreased, with a resultant lessening of the excessive blood flow to her lungs. As a further result, Erin's systemic blood pressure would have been increased when the shunt was opened and the problems with low blood pressure and acidosis avoided.

Odim testified that he relied on the anaesthetists for management of oxygenation and ventilation. He said that this had not been a problem in previous cases. He said he told McNeill that there was too much pulmonary blood flow and asked for her help, but he did not inquire about the amount of oxygen being delivered.

This is a serious question. Hudson and Soder, both of whom are anaesthetists, were questioned on this point. Their testimony indicated that there was nothing inappropriate about the amount of oxygen delivered by McNeill during the stage of the operation when the pulmonary blood flow was excessive. It was suggested that lowering the oxygen might have had a positive effect in terms of blood pressure, but this action carried with it other risks.

■ Finding

It is not possible to state on the basis of the evidence what might have happened. However, it can be stated that McNeill's actions were considered reasonable practice. The underlying issue here, as it is in many of the cases under review, is of the extremely low level of communication and heavy reliance by Odim on what he believed to be 'standard practice' in any given situation.

Was the Blalock-Taussig shunt too small?

Cornel questioned Odim's use of a 3.5-millimetre graft, which he said was difficult to work with and could easily occlude. Cornel said that he preferred to use five-millimetre grafts. He said that the artery providing the blood, not the size of the shunt, governed the amount of blood that was shunted. In his report he wrote:

> Stark and DeLaval recommend use of larger size grafts and I have found that a 5mm graft can be used in virtually every patient. I have used a 4mm graft on only 2 or 3 occasions. Flow is controlled by the subclavian artery rather than by the graft itself. There is a much higher failure rate in small grafts. (Exhibit 353, page 71)

In his testimony, Duncan said that when he wrote his report, he had not heard of anyone using a 3.5-millimetre shunt. He said that in Vancouver, however, where he had subsequently taken up a position at the British Columbia Children's Hospital, 3.5-millimetre shunts were used in that program, with good results. He testified that the issue was the length, as well as the diameter, of the shunt. A long, thin shunt, he said, was more likely to clog. He said that one reason why there was a good chance of the B-T shunt clogging was the fact that the pulmonary vessels were so small. Soder testified that it was common to use 3.5-millimetre shunts at the Izaak Walton Killam Hospital for Children in Halifax, where he worked.

Giddins was asked if he thought that the shunt was too small.

> No, I don't think so. This was a relatively small child, weight of 2.6 kilos. Normally, 3.5 millimetre shunts, in my experience, are standard for normal newborn weights, which is three, 3.5, even 4 kilos. Also she had small lung blood vessels, and the standard size normal newborn size shunt would, I would think, be perfectly adequate for her situation of size and lung blood vessel size. (Evidence, page 4,534)

Giddins was also asked why the central shunt was larger:

> Also, going up a size seemed to me, although I don't remember being part of that decision, it seemed to me a very reasonable decision, in view of the fact they had been having difficulties up until that point in the—not at the very beginning, but up until that point with low oxygen saturation levels. In other words, this shunt had potentially more to do than the first one. This shunt would provide more flow to both sides than potentially just one side. (Evidence, page 4,537)

- Finding

From the testimony that was presented it would appear that the use of a 3.5-millimetre shunt was a reasonable choice, although it led to a higher degree of difficulty for the surgeon.

What led to the shunt failures?

- Finding

There is no conclusive evidence as to why the B-T shunt and the central shunt failed. The evidence indicates that a B-T shunt was an appropriate choice for this child and that switching to a central shunt was also a reasonable decision. The evidence also indicates that at the outset, both shunts were patent—indeed, following the opening of the B-T shunt, Erin had difficulties with too much blood flow.

Witnesses to this Inquest suggested, without reaching firm conclusions, that Erin's problems were related to underdeveloped (hypoplastic) pulmonary blood vessels, low cardiac output, hypoxia and acidosis. These problems were all inter-related and fed upon one another.

As described above, problems with inadequate blood pressure and cardiac output led to both shunts eventually clotting. It should be noted that Odim experienced difficulties with the central shunt when he tried to close Erin's chest. This speaks to the technical difficulties of this procedure, particularly in ensuring that the shunt does not bend or buckle when the chest is closed.

Questions were raised about technical issues. In their joint report, Cornel and Duncan wrote:

> Despite the fact they are not regarded by some as difficult, an aorto-pulmonary shunt is one of the most technically demanding surgeries. The second shunt, despite having been done on bypass, was inadequate at the aortic orifice. (Exhibit 354, page 15)

In his report, Cornel wrote, "The cause of failure of the central shunt is not clear but a technical problem is the most likely." (Exhibit 353, page 72)

This operation was extremely long and accompanied by extensive bleeding. Erin's death was one of these that led Soder to conclude in his report that the:

> **skill and dexterity of the surgeon performing these operations were insufficient for the challenges of successfully repairing infant hearts with complex malformation.** [boldface in the original] (Exhibit 345, page 8)

Should Dr. Andrew Hamilton have assisted in this operation?

- Finding

It was in response to concerns about Odim's skills that Blanchard informed Postl (and, through Postl, other persons involved in the program) that Hamilton would assist Odim in all neonatal surgery. Hamilton should have been involved in this operation.

What was the cause of death and was it preventable?

Erin had been in the operating room for 12 hours because of all the problems and complications associated with the surgical procedure. This would have left her in a weakened condition. In addition, she experienced severe problems with both clotting and bleeding. The clotting of the central shunt, which cannot be definitively explained, led to a loss of blood flow to her lungs and her eventual heart failure.

- Finding

Cornel's conclusion that the failure of the central shunt was due to technical problems, combined with Soder's conclusion that the skill and dexterity of the surgeon were not adequate to the challenge of this procedure, clearly suggests that the death was possibly preventable.

REACTIONS TO ERIN'S DEATH

The death of Erin Petkau brought the long-simmering crisis in the Pediatric Cardiac Surgery Program to a head. Her death, coming so quickly after the death of Jesse Maguire and the complications suffered by JR and ID, demoralized almost everyone involved with the program.

Giddins testified that the Petkau case left him saddened, exhausted and perplexed. He said the outcome had shaken his confidence in the program.

> I remember being shaken, just in the course of events, that all things considered, particularly in the neonatal intensive care unit, that the outcomes and the efforts involved in the preceding months didn't seem to correlate.
>
> Everybody had been working, extraordinarily busy on numbers of both simple cases, more complicated cases, cases that seemed to go without a hitch and cases that seemed to go with lots of hitches. (Evidence, page 4,581)

Youngson had left the OR before the end of the case, having participated in the Petkau case until 1530 hours, when her shift ended. At the time she left, the operation had been progressing well. She learned of Erin's death from McGilton when she came to work the following morning. Youngson testified that she spent the Christmas holidays in a state of desperation. She resolved that when she returned to work in January, she would contact a co-worker whom she believed knew the then-Minister of Health, James McCrae. Through this person, she intended to contact McCrae and communicate her concerns about the program. However, on her first day back at work in January, Youngson was informed by Swartz that the program had been suspended pending an external review, rendering her plan to approach the Minister of Health unnecessary.

McGilton had been involved in the Petkau case until Erin was transferred from the OR to the NICU. When McGilton arrived for work the following morning, she asked how the baby was doing. When Odim told her that the Erin had died, McGilton testified that she broke into tears.

> I just, I left and I went into another room where there wasn't anything going on and kind of got myself together.
>
> I went to the desk, and Karin Dixon asked me if I was okay, and I lost it again.
>
> She phoned Isobel and said that I should go see her, and I did talk to her later that day, and told her that I absolutely couldn't do it anymore. That was it. And what had happened, and it was—she said that she would talk to somebody and do something, but I don't know who she talked to. (Evidence, page 10,648)

Following this conversation, Boyle spoke with Postl:

> There was a case booked for the next day, and ICU was very busy, there was some insistence that that case be done. And I said, Brian, I can't ask those nurses to go back in there, I just can't do that. I said, we are three days, four days before Christmas, ICU is full, we don't have a bed there, we have two kids already, cardiac kids in the unit, or what it was. I said it is hard, I can't find extra staff to staff at this time, and most of all I couldn't get the nurses to go in. (Evidence, pages 32,712–32,713)

McNeill said that when she heard that Erin had died, she experienced a sense of total frustration.

> I think, I mean, it was an accumulation of things up until then. We had had some events in cases that we had been doing over the fall that were difficult to understand or were concerning, and we

> were involved in this process of review that at times felt inadequate, and almost impotent really, and to be involved again on a personal level with a patient who died, just mounted to that sort of feeling. I felt really we weren't progressing, or we hadn't made any strides forward from where we had been in the couple of months before. (Evidence, page 13,653)

She decided that she would withdraw from pediatric cardiac anaesthesia. Before taking any action on this determination, she spoke with Seshia, who questioned her about the course of the operation. Seshia then met with Postl.

> I told Dr. Postl that we had now had problems with two babies with B-T shunts. I told him that we had a baby who was paralyzed, okay, following an arterial switch, which he already knew, and he knew about Jesse Maguire. I indicated that ethically, I was also speaking generically for my colleagues, that we would have difficulty ethically referring a neonate for cardiac surgery here. (Evidence, page 33,583)

Seshia was very disturbed by the fact that two procedures, which in her opinion, were low-risk, had gone so wrong. Postl asked her what she thought should be done. She said that she told him "I don't think we can go on with things the way they are." (Evidence, pages 33,584–33,585) Postl agreed to set up a meeting for later that day.

Seshia then met with McNeill and Swartz, who told her of their concerns over mortality with the program. The two anaesthetists also told Seshia of their concerns about Odim's problems with cannulation and the duration of the procedures.

In his testimony, Postl said he believed that it was on this morning, not earlier in December, that Casiro came to him with his concerns with the program.

POSTL CALLS A MEETING

Later that day, Postl convened a meeting in the HSC's Community Services Building on William Avenue. Present at this meeting were the pediatric section heads involved in the program: Seshia, Giddins, Ullyot and Kesselman.

It should be noted that no one from the Department of Surgery was present. Giddins said that he indicated that it was inappropriate for Odim not to be at the meeting. He said that if Odim was not going to be present, he felt he should not participate. Postl testified that, in response, he told Giddins 'to sit down', that those present were there to discuss the outcomes and that he was expected to participate (Evidence, page 35,566).

Postl told those in attendance that he thought the Pediatric Cardiac Surgery Program should be shut down and asked if they had any thoughts on that. He recalled that all of them agreed, although Giddins did so reluctantly because, as Postl recalled, he was not sure that there was support from the data to make such a decision.

Seshia indicated that the neonatal staff was losing confidence in the Pediatric Cardiac Surgery Program. She spoke both of the deaths of patients and the extended stays in ICU of those infants who survived surgery. Others brought up concerns with the length of bypass times and problems with pacemakers. It became apparent that the neonatologists had lost confidence in the program and were reluctant to refer even emergency cases to it.

A decision was made that such cases would, for the immediate future, be referred out of province. Since no elective operations were scheduled for the Christmas period, this meant that the program was temporarily inactive. Those at the meeting expressed the hope that the PCS program would be reviewed by Lindsay when he arrived in Winnipeg in January 1995.

According to Postl's testimony, the question was raised as to what would happen if the Department of Surgery chose to keep the program active. Postl indicated that his response at the meeting was that he would instruct all Section Heads of the Department of Pediatrics not to participate in the program.

Postl telephoned Craig and Blanchard and informed them of the conclusion reached at the meeting of his section heads. Craig was supportive. Blanchard accepted the decision, although the nature of the program's suspension was not determined at that point. Blanchard took it upon himself to speak with Odim. He told Postl that he would encourage Odim to take his holidays. The following day, Postl informed Wright of the decision. On December 22, Blanchard issued a memorandum stating that Odim would be on vacation for two weeks (Exhibit 19, Document 271).

Blanchard testified that he spoke with Odim, on either December 21 or December 22.

> Well, I can't remember the details of it either, but we reviewed the particular case briefly, and then I told him that there has been a crisis of confidence, and it is not going to be possible to carry on in the near future. And I suggested to him, that being the case, he should take advantage of the gap and take a proper holiday. (Evidence, page 36,667)

In his testimony, Odim recalled that the meeting was with Postl, not Blanchard.

> And I was called into Dr. Postl's office and he told me at that point that the program was going to suspend its activities, that there was too much tension within the hospital coming from the ICU staff and the nursing staff, and that they were simply going to wait until the end of the year when the new chief came to review the program.
>
> And he felt that since they were suspending activities, I probably would need to take a break and I could use a rest, and he suggested that I take a vacation, you know, take my Christmas holidays. (Evidence, page 26,351)

Odim testified that this decision came as a surprise to him. He said that he did not ask Postl any detailed questions about who had raised the concerns.

> It was clear that I was having difficulty rounding the troops towards my ends and my goals and my concept of a team. And it seemed that decisions were just being postponed and postponed, and I was sort of beginning to wonder whether it was really going to happen. And that was sort of my state of mind, and I did not get into a question and answer dialogue with them as to who and, you know, what group, what facet? (Evidence, page 26,354)

Erin Petkau was not the last child to undergo a procedure in the PCS program in Winnipeg, however. On December 21, Odim performed a scheduled ligation of a PDA on a two-and-a-half-year-old child. He performed this surgery after being up all night with Erin Petkau and taking a brief nap at the hospital. On December 22, he implanted a pacemaker in a five-year-old child.

The autumn and early winter had been a tragic and difficult period for everyone involved in this program. In September, the Wiseman Committee had released a report indicating that, after a period of review, serious communication issues had been resolved and the program was ready to undertake high-risk operations. However, by the end of September, Odim had written a letter that indicated a deep sense of frustration and a lack of confidence in his colleagues. This lack of confidence was reciprocated and only increased, as difficulties arose in the operating room and in the intensive care units.

Professionals are expected to rise above personal animosities. However, a team that is meant to perform pediatric cardiac surgery cannot function successfully in the absence of trust and confidence. Nothing was done in the Wiseman Committee to examine the roots of the distrust that program members felt towards each other. Little took place after the Pediatric Cardiac Surgery Program returned to full service to ensure that the team functioned as a team. This became increasingly apparent to the department heads throughout the autumn of 1994 and led to their decision to commission an external review. The decision to have Hamilton assist at Odim's operations represented a positive move in response to concerns and recommendations from a variety of people involved in the program. When Erin Petkau died following an operation in which Hamilton should have been asked to assist, the issues of surgical outcomes and lack of faith in the surgeon came together once more. The department heads had little choice but to stop the program, pending the outcome of a review.

Chapter 9

1995 – THE AFTERMATH OF THE SHUTDOWN

JANUARY TO MARCH 1995

FROM LINDSAY TO WILLIAMS AND ROY

The plan to have Dr. Bill Lindsay review the Pediatric Cardiac Surgery Program had to be abandoned on January 2, 1995. On that date, it was learned that Lindsay would not be taking up his position as the head of cardiovascular and thoracic surgery and cardiology for both the HSC and St. Boniface General Hospital until February 1995. Dr. Robert Blanchard assumed the responsibility of finding someone who could conduct a more immediate review. It was obvious that, with the decision to suspend the program pending a review, time was of the essence.

Because the decision to bring in outside reviewers had financial implications, it required and received the approval of HSC President Rod Thorfinnson. Interestingly, the decision to bring in external reviewers was not taken to the Medical Advisory Committee, which met in both January and February.

Dr. Bill Williams, head of cardiovascular surgery at the Toronto Hospital for Sick Children, and Dr. Larry Roy, a cardiac anaesthetist from the same hospital, were contracted to conduct the review. It was to be conducted with very tight timelines. On January 9, a notice was sent out to all the doctors involved in the program, asking for written submissions that could be sent to Williams and Roy by January 13. The doctors involved began preparing the information they wished the reviewers to see.

On the other hand, the nurses were not informed of the appointment of Williams and Roy, and they were not at that time asked to prepare any written submissions. This was an amazing oversight, given the degree to which the events within the program had affected them individually and collectively and the degree to which they had struggled to bring problems within the program to the attention of the authorities in the hospital. It was, however, sadly in keeping with the way that nurses had been treated throughout the process.

In his submission to Williams and Roy, Dr. Murray Kesselman said that the main issues for the pediatric intensive care unit with the pediatric cardiac surgery program had been confusion over supplies that the surgeon required for bedside care, controversy over sedation and pain relief (analgesia) and post-operative complications.

In her submission, Dr. Molly Seshia noted that the neonatal intensive care unit had not received any protocols from Odim. The NICU nurses early in 1994 had drafted a protocol, but it was still awaiting Odim's input. In a separate memorandum, she asked that Williams and Roy look into such matters as bypass times, mortality rates, complication rates and the quality of diagnostic, anaesthetic and post-operative care.

Giddins's submission was less concerned with addressing problems he saw with the program than with giving Williams and Roy information about what had occurred. Giddins identified three separate phases to the events of 1994. The first phase, from February to March 1994, was marked by what he termed 'understandable' issues, as the team members familiarized themselves with each other. He wrote:

> While I had felt that pre-op discussions had been detailed, academic, and fruitful from an early stage, the intra-op 'network' is obviously more intricate – needing greater time to develop. As acting medical director, I must of course take major responsibility for case selections during this and later periods. (Exhibit 20, Document 284)

His admission that he had a 'major responsibility' for case selection was an appropriate and professionally responsible act, considering the fact that case selection had been such a major concern during 1994.

The second period, that of the crisis of confidence, took place in April and May. Of this period he wrote:

> The anesthesia service in particular appeared uncomfortable with their role in the cardiac OR, and therefore a moratorium was placed on anything other than palliative (closed) procedures and simple open cases (ASD's). By August, the team (as it was now referred to) had proceeded to 'medium' risk procedures (non-infant VSD's), with good success. Vocalization of frustration that there weren't more of these 'medium-risk' cases around! By mid-September, it was felt appropriate by all to proceed to essentially 'all-comers' (understanding that complex situations – particularly neonatal – would be subject to transfer out). (Exhibit 20, Document 284)

The suggestion that "complex situations – particularly neonatal – would be subject to transfer out," however, has to be considered in the face of the fact that none of the "complex neonatal cases" that the team faced in the fall of 1994 were even considered for transfer.

The final crisis of confidence came, he said, in December. In summarizing the situation in Winnipeg, Giddins made the following observations:

> There are, no doubt, weaknesses in the current makeup of the section of Cardiology. As a smaller pediatric centre and heart program, all staff (medical, nursing, technical) have had to be flexible. As the only cardiologist here for the 9 months before the arrival of Dr. Ward in July, it was impossible to provide any more than a consultation service to the hospital. Since his arrival, things have been little better, considering the inevitable medical 'backlog' that had developed. This has had direct effects on everything from our ability to get acquainted with transesophageal echo techniques to being more involved at the critical care bedside. While Dr. Ward is extremely accomplished, this is still his first staff appointment. Both of us would be considered junior in many centres. We have done our best to help short of direct bedside management, which with our current clinical demands would be impossible. (Exhibit 20, Document 284)

On January 12, 1995, Odim forwarded a letter to Williams, describing his perception of the issues at the hospital. A portion of that letter simply reprinted excerpts from his September 26 letter outlining the May 17 withdrawal of services. Odim then summarized the Wiseman Committee experience. He stated that among the issues dealt with at that time were the mortality and morbidity rate, a lack of confidence in the surgeon, communication issues, the learning curve that the surgeon and cardiologist faced, proper decorum in the OR and the issues facing a pediatric cardiac surgery program in a small market. He concluded by saying:

> Clearly, I have had some difficulty establishing myself as the captain of the ship. This is further unmasked by the lack of local leadership in cardiac surgery, cardiology, and anesthesia. (Exhibit 20, Document 286)

Ullyot prepared the anaesthetists' submission. It highlighted concerns about case selection, surgical results, and the program review and case review process. Her submission noted that the Wiseman Committee had not fully addressed the concerns that had led the anaesthetists to withdraw their services. It also emphasized the lack of an overall strategy for the program's development and called for a review of the number of anaesthetists required for the program. Finally, her report stated that the nurses must be involved in the review process.

Blanchard prepared a lengthy submission that is worth quoting in detail.

> My own perspective is generic and necessarily non-technical. A serious error on my part when Jonah arrived was failure to anticipate the potential for difficulties in introducing a new surgeon without a senior mentor or team-builder. When Kim Duncan joined our program in July 1986, [Jary] Barwinsky had been carrying on a modest program of closed cardiac surgery at the Children's Hospital and served to introduce Kim into the system and assist him. More important, George Collins was the father-figure for the entire Variety Heart Program at the Children's Hospital and was a major influence in helping Kim Duncan over the rough spots, especially at the beginning of his activities here. After Kim Duncan left in August 1993, the program was discontinued pending the recruitment of a Paediatric Heart Surgeon. When Jonah arrived, there was no cardiac surgeon with any interest or recent activity at the Children's Hospital and George Collins was no longer with us. Unfortunately, we left Jonah to fend for himself in a new environment with different procedures than he had previously experienced. He did not know our team and the team did not know him. To make matters worse, Jonah has not, it appears, established strong links with easy communication among some of the key players, especially Anesthesia. From my perspective, the anesthetists behaved in an adversarial fashion without making allowances for the situation of a new junior surgeon who should have been the director of the team. It appeared to me that, when things appeared to go wrong, the anesthetists and some nursing staff were ready to believe that this was entirely the fault of inadequate surgical management.
>
> Nonetheless, communications were not established from either side to try to sort these things out and I, at least, was not aware of the serious nature of the problem until the anesthetists unilaterally boycotted the program. We then set up a series of meetings chaired by Dr. Nathan Wiseman, Director of the Paediatric Surgical Services. His report is attached along with my response to it that may have been too optimistic. During this period I interviewed those who have worked with Jonah as assistants or colleagues and was told that he is technically capable, if somewhat slow. He has also been considered to be knowledgeable. The Anesthetists and staff at the General Hospital (Adult) have found his operative procedures to be on par with our average adult cardiac surgeons. I am not capable of judging his surgical skills nor surgical judgement directly. I tried to get Jonah to work more closely with another new recruit whose primary activity is adult cardiac surgery, Andrew Hamilton. Unfortunately, Jonah has not always availed himself of this individual's assistance and support and one is left wondering why he did not do this. My direct discussions with Jonah lead me to believe that he is open and willing to work things out. (Exhibit 29, Document 391)

He concluded the letter by stating:

> From my perspective, the problems are as follows:
>
> - A junior solo paediatric heart surgeon without a mentor.
> - Jonah seems not to be sufficiently clear and direct in communications.
> - When things go wrong in the operating room, it is reported Jonah appears to become flustered at times.
> - There may be problems in judgement, both for case selection and in the conduct of some problems when things are not progressing as anticipated. I have no direct indication of this, but from interviewing Jonah I wonder whether he always scans the whole horizon of possibilities.
> - Jonah maintains a dignified and calm exterior. Perhaps this is misinterpreted by some of the nursing staff as lack of caring. My own reading of Jonah is that he is a dedicated and caring individual who certainly is willing to work hard to develop a good program. It would appear, however, that he is somewhat reluctant to ask for help, advice, or moral support when it is needed.
> - There are probably too many Anesthetists.
> - There are two Critical Care Units dealing with a small volume of difficult post-operative patients.
> - We failed to spend time at the beginning to work through the whole system, using simulations and trial runs. (Exhibit 29, Document 391)

On January 13, 1995, Blanchard sent a memorandum to sixteen doctors involved in the program, advising them that Williams and Roy would be present at the HSC on January 25 and urging them to make themselves available on that day.

However, once again the nurses were left out of the loop. They had not been given advance notice to prepare submissions to the Williams and Roy Committee; nor were they given the same notice that doctors received of the impending visit. The director of pediatric patient services, Isobel Boyle, belatedly received notice of the Williams and Roy process. When she brought her concerns to the head of the Department of Pediatrics, Dr. Brian Postl, she said he indicated that the nurses had to be involved in the process. It fell to Irene Hinam and Carol Youngson to organize the nurses' response. Hinam approached both the NICU and PICU nurses and assisted them in preparing reports (Exhibit 20, Documents 278 M, 278 N, 278 O).

Their report stressed:

- Lack of preparation at the start of the program;
- Poor planning;
- Odim's poor understanding of hospital protocols;
- Poor communications with nurses and families;
- Lengthy operations;
- Increased need for heart pacing;
- Deaths of children who were not high-risk;
- Monitoring lines falling apart;
- Post-operative bleeding;

- Concern over longer than expected stays in ICU; and
- Poor morale.

On January 25, 1995, Williams and Roy met from 0730 hours to 1900 hours with individuals involved in the program. From their itinerary, while it would appear that they met with operating-room nurses, it does not appear that they spoke with any of the NICU or PICU nurses.

THE WILLIAMS AND ROY REPORT

On February 3, Williams and Roy sent their report to Blanchard. The report listed ten conclusions. Williams and Roy stated that there was evidence to question Odim's technical competence; that Odim might have been judged unfairly since he had attempted to adopt the HSC's methods rather than import his own preferences; and that the program had been poorly supported by the HSC from the outset. On this last point, Williams and Roy commented that it appeared that the program lacked protocols for effectively resolving disputes over patient care. It should be noted that Williams and Roy specifically stated that their report "neither exonerates nor condemns the present surgeon." (Exhibit 20, Document 364) They concluded that there was a crisis of confidence and identified the hostilities that have been described by this Inquest report. They also noted that their work was:

> ... hampered somewhat by the lack of relevant data. Information relating to morbidity and length of stay were unavailable. Those interviewed often referred to these issues but were unable to support their contentions with data. This program needs to establish an accessible database. (Exhibit 20, Document 364)

Other key issues that the report identified were the long periods of bypass, the large number of people involved in providing both anaesthetic and post-operative care and the lack of an identifiable budget for the program.

Their report contained two proposals for consideration. The first was that the program be consolidated with the program in Saskatoon.

> An amalgamated single unit would be cost effective because of an economy of scale (which would need to be proven, although there is data to support such a conclusion) and would provide a critical mass of patients for focused expertise including two pediatric cardiac surgeons. If the program is moved to Saskatoon it solves all of the above problems in a single stroke. If the unit is located in Winnipeg, a major restructuring is required. (Exhibit 20, Document 364)

The report noted that in the United States, larger units were not only more cost effective, but had better morbidity and mortality rates than smaller units.

If the program was to remain in operation in Winnipeg, they suggested a complete restructuring. This would involve the creation of a cardiac program run by a triumvirate of a nurse administrator, a doctor and a hospital administrator.

> All aspects of the cardiac service, namely surgery, cardiology, cath lab, operating room, ward, outpatient clinics, cardiac nursing, intensive care should be organized and run by the 3 program administrators. These three individuals should be directly responsible to the vice president or the CEO of the hospital and responsible for all aspects of the cardiac program including the budget. (Exhibit 20, Document 364)

They further stated that Lindsay needed to make this program his first priority. To do this, they recommended that the chief of surgery assist at all pump operations for the coming year. This was to allow an assessment of the surgeon, to provide consistency, and to resolve disputes. They also recommended that the chief of surgery be available to ensure that case selection was appropriate and that issues, such as the transfer of all patients to a single ICU, were resolved quickly. Williams and Roy believed that between two to three anaesthetists should be involved in the program, that all cases should be dealt with by a single ICU, that nurses had to be involved in program decision-making in a meaningful manner and that two more cardiologists should be hired.

RESPONDING TO THE REPORT

Blanchard received the report on February 7. Two days later, he met with Postl, Craig and Lindsay (who by now had arrived) to review the report. They decided that it would be necessary to place the PCS program on hold while the two options proposed by Williams and Roy were fully explored. They anticipated that this process might take six months. Craig informed Thorfinnson of the decision the following day. Craig and Thorfinnson arranged for the three department heads to meet with Thorfinnson, the HSC vice-presidents, and representatives of the Manitoba government on the morning of February 13. A meeting of all the HSC personnel involved with the program was set for noon on February 14. The Williams and Roy report was kept confidential: section heads were allowed to read it in the office of their department head, but they were not allowed to remove it from the office.

Present at the meeting on February 13 were Blanchard, Craig, Postl, Thorfinnson, the four HSC vice-presidents (Susan VanDeVelde-Coke, Helen Wright, Dr. J.D. Sutherland, and John Horne) and Jim Rodger, the assistant to the HSC president. Two representatives were present from the Manitoba Government: the Deputy Minister of Health, Dr. John Wade, and the Assistant Deputy Minister of Health, Tim Duprey.

At the meeting Blanchard summarized the Williams and Roy Report and its recommendations. All three department heads spoke in favour of restructuring the current program rather than switching it to Saskatoon. According to notes taken at the meeting by Rodger, the three also indicated that a new surgeon was needed and that it was not possible to rebuild around Odim. According to Rodger's notes, Wade said that he did not think that Manitoba had the population to provide a pediatric cardiac surgeon with the volume needed to maintain her or his skills.

Thorfinnson stressed the need to have a media strategy to deal with the issue. It was agreed that the program would be suspended for six months and that a news release would be issued the following day.

THE ROLE OF THE PRESIDENT AND VICE-PRESIDENTS

In their testimony, several of the vice-presidents indicated that they were surprised by the information that they had received at this meeting. Wright had been kept briefed by Postl of his concerns and knew in late November or early December that he had been thinking of closing the program. Wright testified that, when she took on her new responsibilities on June 1, she was briefed by Dr. Agnes Bishop, the outgoing head of pediatrics. Bishop had told Wright that there had been problems with the Pediatric Cardiac Surgery Program, but a multidisciplinary committee was looking at the issue. Wright said that she may have briefed Thorfinnson about this matter at the end of June, but it would have been simply to say that a committee had been set up to deal with problems. Wright said that she had not seen the Wiseman Committee interim report when it was prepared in the summer of 1994, but had been briefed about its contents. The one report from her mentioning the program in 1994 that went to the Board of Directors of the HSC simply indicated that a new surgeon had been hired and that the program was providing full service.

VanDeVelde-Coke testified that before the meeting she had not known about either the withdrawal of the anaesthetists from the program or the existence of the Wiseman Committee.

Sutherland said that he felt the department heads should have informed him of the events of May 1994. He did add, however:

> These three department heads, Dr. Bishop, Dr. Blanchard and Dr. Craig, were three of the people on whose judgment I relied on greatly. They were excellent department heads, and had good insight, good wisdom. And if they came to me and said, Ian, we have got a problem, and this is how I have dealt with it, and, in fact, looking at how they dealt with it in terms of setting up a committee of individuals who were involved in delivering the health care, and getting them to review it, and getting their buy in to re-establishing it, I don't think I could have done any better than that. (Evidence, page 38,437)

In his testimony, Thorfinnson said that before the summer of 1994, he had been made aware there were some problems in the program, but had been assured that they were being addressed. He was not certain how he had been given this information, but thought it might well have been from Wright. Thorfinnson testified that, with the benefit of hindsight, the details of the anaesthetists' action should have been brought both to his attention and to the attention of the Board of Directors. Again, he indicated, it would have been unlikely that either he or the board would have taken any action other than to allow the Wiseman Committee to do its work. Thorfinnson also said that he thought the matter ought to have been addressed by the MAC. He did not think it would have been appropriate to have been brought up at the Nursing Council. While nurses were involved in the program, it was in his opinion a medical and surgical issue, not a nursing issue.

Thorfinnson testified that Blanchard spoke to him about the program's problems twice in 1994, once in early December and once following the decision to stop performing surgery pending a review. At the first meeting with Blanchard, Thorfinnson said, Blanchard had said there were concerns with surgical outcomes and that he was monitoring the program. Thorfinnson testified that he asked if there were problems with Odim's competency, a question that Blanchard indicated that he could not answer. In terms of the manner in which the issues were reported to the Vice-Presidents and the President, Thorfinnson said:

> It has become I think very clear to the vice-presidents and no doubt to the people who report to them that any activity of this magnitude should be reported up very quickly. And that's the major impact of that reporting mechanism. (Evidence, page 46,522)

Blanchard testified that he met with Odim on February 13 and informed him that the program was being shut down for at least six months. He also told him that if the program were to be revived, Odim would no longer be the surgeon. Blanchard advised Odim to seek another appointment and requested that he resign immediately. Blanchard testified that Odim indicated that he would resign. However, Odim never submitted a resignation. He testified that he told Blanchard he needed time to consider whether or not to resign. He said that he spoke with Blanchard by telephone later that night and told him that he did not intend to resign. Blanchard did not pursue the matter, but Odim did not participate in any more pediatric cardiac surgery at the HSC after that date.

On February 14, 1995, the HSC issued a news release that read in full:

> The Health Sciences Centre announced today that the Pediatric Cardiac Surgery Program will undergo an intensive six-month review to ensure that the best possible cardiac care service is available to young Manitobans and their families. This decision was made because patient outcomes have not achieved standards which the hospital hoped for when the program was re-introduced in February 1994.
>
> An external review of the Pediatric Cardiac Surgery Program was commissioned by the Health Sciences Centre in January 1995. The report of the external reviewers highlighted a number of areas in which the program could be improved, including staffing patterns, resource allocation and the meeting of outcome objectives. Fundamentally, the review questioned whether, in a population of about one million people, there are sufficient numbers of children requiring heart surgery to maintain the clinical expertise required.
>
> In the course of the next six months, the Health Sciences Centre will consider a variety of steps which might be taken to optimize the activities of the program. Such steps might include more formalized links with other centres where pediatric cardiac surgery is performed, reallocation of financial resources in support of the program and revisions to program staffing patterns.
>
> Patients requiring pediatric cardiac surgery have been transferred to Saskatoon or Toronto since Christmas 1994 and will continue to be transferred until the Centre's review has been completed. This practice, which has been routinely followed in the past, will ensure that Manitoba's children continue to have prompt access to the full spectrum of pediatric cardiac services during the six month review period. (Exhibit 43)

Not surprisingly, this news release generated a considerable degree of coverage. That coverage was not without its negative impacts.

THE PARENTS

Unfortunately no thought had been given to the families of the 12 children who had died in 1994. With few exceptions, they heard about the shutdown through the media. The news shocked and distressed them. For a number of families, the news was also disturbing because they had yet to receive what were, by then, long-promised autopsy reports. It was, in fact, only at this point that the Terziskis were informed that no autopsy had been performed on their son.

Not surprisingly, the families began phoning the Heart Centre and the media. For its part, the HSC realized that a response was necessary. Lois Hawkins and Cathryn Martens, co-ordinator of the Patient Representative Office, began contacting families, although in many cases the families had already contacted them. The families were offered the opportunity to meet with HSC staff.

From the evidence, it appears that the families of Gary Caribou, Jessica Ulimaumi and Erin Petkau were never directly contacted. Hawkins testified that she spoke about the events with representatives of a family services agency in Lynn Lake that was providing service to the Caribou family. Hawkins said that she was given to understand that the family was "all right." (Evidence, page 12,226). In her testimony, Charlotte Caribou said that she only learned about the shutdown by reading about it. She also testified that her common-law husband had made an unsuccessful attempt to reach Odim by telephone. Hawkins testified that she communicated with northern medical officials, who told her that the Ulimaumi family did not wish any further involvement with the hospital. That information was confirmed by Christina Kopynsky, Q.C., Counsel for the Inquest, who travelled to Inuvik to meet with the family. Barbara Petkau testified that she was not contacted by the HSC.

Contact was also made with the Stills, who chose not to come to Winnipeg for a meeting. The Bichels, Pillers and Terziskis also chose not to attend a meeting.

Meetings were held with the families of Vinay Goyal, Aric Baumann, Marietess Tena Capili, Ashton Feakes and Jesse Maguire. The meetings were attended by family members (and, in some cases, friends), Odim, Hawkins, Martyn and—depending on who had been involved with the case—either Ward or Giddins. At the meetings, the doctors would review the medical issues and the family members would ask questions. From the evidence that was presented, these meetings varied considerably in tone and nature. Laurie Maguire, the Tena and Capili families and the Feakes were not satisfied with their meetings. The Tena and Capili families described the meetings as 'a run-around', while others were frustrated that no one at the meeting was able to explain why the program had been shut down. Indeed, several testified that Odim and Giddins essentially told the families that they had no explanation as to why the program was being shut down.

It is clear that the program's history and the summer shutdown were not properly explained to the families; nor were they shown the Williams and Roy report, let alone advised of its existence. Finally, even when there were known facts that should have been brought to a family's attention, such as the suture narrowing that had been identified in Marietess Tena Capili's autopsy, this information was also not shared with the family.

There were also expressions of support for the program. Dr. J. Bergman, the pediatric chief resident, wrote Odim a letter of support on behalf of all the pediatric residents at Children's Hospital. Dr. Denis Hosking, the section head of Urology, also wrote Odim a letter of support.

Giddins received a letter of support from the Manitoba Pediatric Society on February 23. On March 7, 1995, Odim distributed an open letter to his colleagues. Along with it was an eight-page statistical summary of the program. In his letter, Odim wrote:

> This information is in the public domain. It has been presented at our open year-end mortality and morbidity rounds. In addition, both the executive branch as well as concerned department heads have had copies of this information over the last two months.
>
> As a matter of professional courtesy, you deserve to have an account of the program's activity during this period. The on-going media attention is affecting all of us at HSC. I am sharing the facts with you to clarify the rumours and distortion of the press. (Exhibit 20, Document 311)

In his testimony Thorfinnson testified that he was surprised by Odim's behaviour but took no action in response to his release of this documentation.

Letters of support were also sent to Odim from families whose children he had operated upon. In addition families whose children would now have to leave the province also raised their concerns.

THE QUALITY ASSURANCE COMMITTEE

The events in the Pediatric Cardiac Surgery program in 1994 were never discussed or reviewed by the HSC's Quality Assurance Committee, which is a committee of the HSC's Board of Directors. Thorfinnson testified that this was because the matter was not brought to the Committee's attention. He indicated that he believed that it should have been brought to the Committee. However, he also stated that he believed the Committee would have allowed the Department Heads to deal with the issue.

DELAYS IN THE AUTOPSY REPORTS

Autopsies were conducted on nine of the 12 children who died in 1994. In the cases of Gary Caribou and Vinay Goyal, the families requested that there be no autopsy. In the case of Daniel Terziski, a miscommunication led to a situation where an autopsy that should have been performed was not performed.

In the nine cases where autopsies were carried out, the autopsy itself was performed within a short period of time (generally within 48 hours), but there were extremely long delays between the autopsy and the completion of the autopsy report. The Baumann family had to wait over five months, while several other families had to wait over four months for the reports to be completed. In the Still and Piller cases the reports were completed quickly. However, it is also apparent that other autopsy reports were completed only because of the pressure that mounted following the closure of the program in February 1995.

It appears from the evidence that five autopsy reports were completed in February 1995, within a ten-day period following the closing of the program. If the program closure had not generated intense demand from the parents for these reports, then it would appear to be reasonable to assume there might have been further delays in completing those reports.

Dr. Susan Phillips, the Chief Pediatric Pathologist at the HSC, testified that during 1994 she believed pediatric pathology to have been understaffed. She pointed to efforts that she had made to have a third pathologist appointed to assist her and Dr. Joseph de Nanassy. However that position was not filled.

In 1994 Phillips and de Nanassy did 197 autopsies. They also examined 2,271 pediatric surgical specimens. These are specimens removed from living children, usually during operations. In general, the specimens must be examined and reported on within 24–48 hours.

The *Fatality Inquiries Act* states that, where an autopsy has been ordered by the Chief Medical Examiner, an autopsy report must be submitted to the Chief Medical Examiner's Office within 30 days of the autopsy. There is no deadline if an autopsy is not ordered by the CME. Phillips testified that she understood that requirement to mean within 30 days of the completion of all tests, not 30 days after conducting the initial autopsy. She pointed out that many tests results do not come back until well after the 30-day period. She stated that it was her goal to have the autopsy reports to the CME within three months of conducting the initial autopsy. Using that as a standard, the HSC met this deadline in six of nine cases.

However, the Act itself is clear: a report is be submitted within 30 days of the autopsy. It is also clear that this report must be comprehensive enough to allow the CME to make the crucial decision as to whether to proceed with further investigation or even to order an inquest.

One of the factors that seems to have contributed to the ongoing disputes that existed within the program was the lack of specific information about, or disagreements over, what had occurred. The pathologist's report is one tool that can be used to help resolve such disputes and questions. Unfortunately, the delay in the autopsy reports meant that decision-makers lacked access to valuable information. The narrowing of the cannula sites in the Tena Capili case should have been made known by October before the operations on Erica Bichel, Ashton Feakes, Jesse Maguire, and Erin Petkau were undertaken.

In his testimony to the Inquest, Markesteyn indicated that his office was not able to enforce speedier completion of autopsy reports.

THE COLLEGE OF PHYSICIANS AND SURGEONS

As noted in Chapter Four, the College of Physicians and Surgeons of Manitoba (CPSM) created standards committees at all Manitoba Hospitals. In 1994 the Children's Hospital Standards Committee reported to both the HSC Centre-Wide Committee and the CPSM's Paediatric Death Review Committee. A panel of three surgeons reviewed surgical deaths in Children's Hospital and sent a report to the Children's Hospital Standards Committee. That panel did not make its report until the final autopsy on the child had been completed (in those cases where there was an autopsy). Once that report was prepared, Dr. Nathan Wiseman, a member of both the Standards Committee and the panel of three pediatric surgeons who reviewed cases, presented the report to the Standards Committee. The two other members of that panel were Odim and Dr. Postuma. Wiseman was asked if there was not a conflict of interest in Odim reviewing his own cases. He said in response.

> It's difficult. This is the problem, there is no peer who is in a position of being able to be an expert in this area. We dealt with this for X number of years with Kim Duncan, where we sat down and reviewed cases with him; and it's dealt with basically by sort of challenging and asking questions and attempting to get objective answers, and trying to be satisfied that those answers are reasonable and appropriate.
>
> There is definitely, I mean, if it gets down to the nitty-gritty, there is a phenomenon of mea culpa. People are very willing, maybe not always, but very willing to say, look, I screwed up. You have to recognize your own failings and put them on the table, and it happens.
>
> ...
>
> *THE COURT:* You don't have a policy then of excluding from the committee a member whose cases are actually being under the review?
>
> *THE WITNESS:* At the level of our sort of standards fact gathering to present to the hospital committee, no. At the level of the hospital committee, then there is no participation from the individual. The second level of review is—
>
> *THE COURT:* That's Dr. Tenenbein's committee?
>
> *THE WITNESS:* Yes. (Evidence, pages 40,748–40,749)

The fact that Odim was a member of the panel of surgeons that reviewed each surgical death for the Children's Hospital Standards Committee had the potential for a serious conflict of interest when the death involved one of Odim's patients. His involvement was called for because he was the only pediatric cardiac surgeon in Manitoba. A specialist in the field could have been brought in to assess the cases, thereby eliminating any potential conflict. That was not done in 1994, and the results of that process remain tainted by that fact.

The Children's Hospital Standards Committee would discuss the case and a report would be forwarded to the the CPSM's Paediatric Death Review Committee. There the case would once more be summarized and reviewed by the committee. Dr. Milton Tenenbein, the chair of the Children's Hospital Standards Committee, was also a member of the Paediatric Death Review Committee, as were Wiseman and Phillips.

All 12 deaths under consideration by this Inquest were reviewed in this manner. Those reviews did not take place in a timely manner. That was a matter of some concern to members of the section of pediatric anaesthesia. In October 1994 the pediatric anaesthetists wrote to both the panel of three surgeons and the Children's Hospital Standards Committee, urging them to expedite their review of the cases. Their concern persisted. On February 20, 1995, Dr. Carol Bachman, an anaesthetist, wrote a letter to Tenenbein on behalf of the pediatric anaesthetists, stating:

> It is our hope that all children who had cardiac surgery and who died in the perioperative period be reviewed by the Standards Committee as soon as possible.
>
> I realize that it is not uncommon for several months to elapse between a death and its review by the Standards Committee. Also, a separate review process had been instituted in the summer of 1994 for these specific cases, which may have delayed final review and recommendations, by the Standards Committee. (Exhibit 20, Document 295)

While it is not possible to determine from the evidence when the Children's Hospital Standards Committee reviewed each of the 12 deaths, it is clear that most of the reviews did not take place until after the program had been closed down in 1995. In his testimony, Wiseman testified that by January 1995 the surgical panel would have reviewed only those deaths that occurred before July 1994. According to a letter sent from the College of Physicians and Surgeons of Manitoba's counsel to this Inquest, by the date of the program closure the College had not assembled any data that would enable it to evaluate the program and/or form opinions about any trends (Exhibit 20, Document 360).

This suggests that, if the Children's Hospital Standards Committee had reviewed any of the 12 cases by February 14, 1995, it had not forwarded them to the Paediatric Death Review Committee. In his testimony, Tenenbein said that the committee attempted to deal with cases within six months during 1994. However he acknowledged that the process of review of the Paediatric Death Review Committee could be slow. In fact, he said (in response to a question about the length of time that the committee took to prepare its report), getting it out within two years of the year under review was considered a significant accomplishment.

In light of the public debate that followed the February 14, 1995, announcement, the Children's Hospital Standards Committee introduced new timelines. On March 14, 1995, Tenenbein wrote to Dr F.W. Orr, the head of Pathology for the HSC. The letter stated that the Standards Committee wanted provisional autopsy reports in 72 hours (unless it was a complex case when the deadline would be two weeks) and final reports in three months. If there were outstanding toxicology reports, the autopsy should be released with the caveat that the toxicology reports could change the final report. Orr agreed to the proposal. (Exhibit 322)

The Paediatric Death Review Committee issued an annual report for 1994 in January 1997. The report commented on all 12 deaths under review by this Inquest. The report concluded,

> Of the 12 cases, the committee classified four as being possibly preventable with improved medical management. (Exhibit 156)

While they were not named in the report, the cases were summarized. It is apparent from the summaries that the committee was referring to the cases of Jessica Ulimaumi, Vinay Goyal, Marietess Tena Capili and Jesse Maguire. The report concluded that:

> There is a lengthy delay in information reaching the College through the normal Standards route. There is a need for a timely, accountable, concurrent audit process at the hospital level whenever complex multidisciplinary programs of this nature are undertaken in children. Educational action at this point has consisted of letters to the physicians involved. (Exhibit 156)

THE OFFICE OF THE CHIEF MEDICAL EXAMINER

As noted earlier, the death of any child must be reported to the Office of the Chief Medical Examiner. That was done promptly in each of the cases under examination. In each of the cases, a Medical Examiner Investigator made a timely visit to the HSC to look at the chart and to meet with Odim. The investigators differed from case to case, so that the same investigator was not involved in every case. That fact may have contributed to a slowness in the response of the CME's Office to the issues that were apparent from the cases. Apparently no trend in the deaths was noted, and information relating to the program itself and the changes that had occurred within it (including the arrival of a new surgeon) was not obtained. The fact that the anesthetists had withdrawn their services in May due to concerns over poor results, that there was dissension within the program, and that there had been a slowdown in the types of procedures the program was doing, had not been communicated to the CME's Office.

It is the policy of the CME's Office to authorize an autopsy when a child dies during or immediately after surgery. Parents are normally told of this policy. In the cases under discussion, the surgeon also requested the parent's permission to hold an autopsy. In the case of two children, Gary Caribou and Vinay Goyal, the families requested that there be no autopsy. Based on the Medical Examiner Investigator's report that there were no apparent issues with those cases, the Chief Medical Examiner chose to honour the family's request.

In the case of Daniel Terziski, no autopsy was held, despite the fact that the parents were amenable to an autopsy and the fact that both Odim and the Chief Medical Examiner's office believed that one should have been conducted. As discussed earlier, it appears that an autopsy was not held because of a failure of communication.

In eight of the twelve cases, the Medical Examiner Investigator concluded that there was no need for further investigation. In four cases, however, further investigation was authorized: those of Jessica Ulimaumi, Erica Bichel, Jesse Maguire and Erin Petkau. In the case of Jessica Ulimaumi, it was concluded that her death was the result of 'therapeutic misadventure' and the matter was referred to the Children's Inquest Review Committee, a multidisciplinary committee convened by the Chief Medical Examiner. The committee reviewed the matter and, aside from referring the file to the Paediatric Death Review Committee, took no other action. It should be noted that CME investigations usually take place following the completion of an autopsy. Aside from the Bichel case, the only other CME-ordered autopsy completed before the program was closed was that of Jessica Ulimaumi.

Upon reviewing the autopsy in the Bichel case, the Chief Medical Examiner did not refer the case to the Children's Inquest Review Committee. Markesteyn concluded that the circumstances of the death in that case did not warrant the holding of an inquest.

Throughout 1994 the Chief Medical Examiner was not aware of the events taking place in the Pediatric Cardiac Surgery Program. In addition, the Chief Medical Examiner's office was not made aware of the shutdown in December 1994. The Chief Medical Examiner was not informed of the review conducted by Drs. Williams and Roy, nor of its results. The Chief Medical Examiner's office was not consulted about the findings of the review; nor was the Chief Medical Examiner involved in the decision to suspend the program for a further period of six months.

Markesteyn testified that he became aware of the events in the program only when he read about them in the newspaper in February 1995. He then undertook further investigations and wrote to the HSC, asking for all documentation on the cases. The CME's office contacted the parents to inform them of the investigation. He contracted Dr. Walter Duncan to undertake a review of the deaths on his behalf. After receiving Duncan's report, Markesteyn consulted with members of the Children's Inquest Review Committee and decided that it would be appropriate to establish an inquest into the 12 deaths.

Section 3

Chapter 10

FINDINGS AND RECOMMENDATIONS

INTRODUCTION

The preceding chapters have recounted the events surrounding the deaths of 12 children during or after pediatric cardiac surgery at the Winnipeg Health Sciences Centre in 1994. While each of these children died under very specific circumstances, common issues have arisen from the evidence presented to this Inquest. They point to the conclusion that the serious organizational and personnel problems experienced by the Health Sciences Centre's Pediatric Cardiac Surgery Program during 1993 and throughout 1994 may have contributed to the deaths of some of these children. This leads to a central finding of this Inquest:

- **Finding**
  The evidence suggests that, during 1994, the Pediatric Cardiac Surgery Program at the Health Sciences Centre did not provide the standard of health care that it was mandated to provide and which parents believed, and had a right to expect, that their children would receive.

While some of the problems that the program faced related to the abilities and conduct of specific individuals, other problems were largely systemic in nature. These systemic problems related to the structure of the HSC, in particular to hospital policies and procedures governing staffing, leadership, teamwork, communication, decision-making and quality assurance. Weaknesses in all of these areas led to problems in the procedures and outcomes of the program. As a further result of systemic failures, the issues surrounding the abilities and conduct of certain team members, and the performance of the surgical team itself, were not dealt with in a timely or effective manner.

This chapter is devoted to setting out those findings and recommendations that are essential for ensuring that the situations that occurred in this program in 1994, and the manner in which these children died, will not be repeated. They include, among other things, the question of whether or not the HSC should continue to attempt to maintain a Pediatric Cardiac Surgery Program.

The overall objective of these recommendations, however, is to prevent a similar situation from arising at the HSC as occurred in 1994. The evidence suggests that this objective can best be met by strengthening program planning, establishing appropriate preventive measures and improving risk management.

The evidence also makes it clear that improving interpersonal and team communications and devoting resources to building and maintaining a properly functioning surgical team are keys to any similar future programs.

Meeting the latter objective requires that the culture of health-care institutions must change. It is particularly important that medical professionals provide parents with more information than was done in these cases. Also of particular importance is that nurses not be treated by doctors and hospital administrators as undertrained subordinates, whose concerns can be readily dismissed as emotional responses to tragic outcomes.

The ubiquitous nature of human error in a medical setting must also be accepted and better understood, and its occurrence no longer treated as a moral failing. Methods must be developed to reduce the frequency of medical and human errors within hospitals, trap such errors as they occur and reduce their impact.

The thrust of the recommendations in this chapter is not punitive. The need is to improve the health-care system so as to prevent the recurrence of events that occurred in 1994. It is necessary to accept that the health-care system will not improve if people act solely on the basis of a fear of consequences for themselves or their careers. Instead, the recommendations are intended to establish a structure within which highly skilled and talented people can establish a health-care team that continually works together to provide a high standard of care. All of the comments and recommendations in this chapter are intended to fulfil this objective.

However, there are recommendations that do call upon appropriate existing agencies to examine this report with a view to determining if any disciplinary or other action is required for those whose performance and actions may not have met the appropriate standard for the positions they held.

This rest of this chapter is made up of eight sections. They include findings and recommendations with regard to:

- The loss and recruitment of program staff before 1994;
- Problems within the Pediatric Cardiac Surgery Program during 1994;
- The treatment of nurses;
- The treatment of the families of the deceased patients;
- Monitoring of issues and problems within and outside the HSC;
- Human and medical error;
- The future of pediatric cardiac surgery in Manitoba; and
- Referral to the College of Physicians and Surgeons of Manitoba.

Each section contains findings, explanatory text and recommendations. The findings and recommendations flow from information already presented in previous chapters. For this reason, the explanatory text has been kept to a minimum.

THE LOSS AND RECRUITMENT OF PROGRAM STAFF BEFORE 1994

LOSS AND RECRUITMENT OF PROGRAM STAFF

▪ **Finding**

The evidence suggests that the loss of and failure to replace professional medical staff from the Variety Children's Heart Centre in 1992 and 1993 represented a serious erosion in the ability of the Pediatric Cardiac Surgery Program to continue to provide the level of service that it had previously provided.

▪ **Finding**

The evidence suggests that the impact on the Pediatric Cardiac Surgery Program of the loss of medical staff in and before 1993 was not appreciated by the heads of the responsible departments.

▪ **Finding**

The evidence suggests that the HSC's recruitment of a pediatric cardiac surgeon in 1993 to replace Dr. Kim Duncan was flawed.

▪ **Finding**

The evidence suggests that the process of replacing Dr. George Collins as head of the Variety Children's Heart Centre following his retirement in 1993 also was flawed.

Those responsible for staff replacements in 1993 and 1994:

- were slow to begin the process of recruitment and replacement;
- took too long to find capable replacements once they did begin;
- relied on inadequate professional staff recruitment processes; and
- failed to take appropriate steps to address case load and other program issues when positions were left vacant for extended periods of time.

Two staff cardiologists had left the pediatric cardiac surgery program during 1992–93 and had not been replaced by the time of their departures. In addition, Dr. Kim Duncan, who gave notice in April of 1993 of his intention to leave the hospital in July for a position in the U.S.A., was also not replaced by the time he had left. While Duncan was under no obligation to provide any greater notice than he gave, the period of time between his notice and departure was also likely insufficient to ensure that a replacement would be in place by the time he left.

The evidence also suggests that there was confusion as to who was on the formal search committee established to find a candidate to replace Duncan. While Drs. Blanchard and Giddins testified that they believed that Dr. George Collins was a member of a search committee for the new pediatric cardiac surgeon and responsible for assessing the candidates' surgical skills, Collins testified that he did not view himself as a member of any such committee. Accordingly he had only peripheral involvement in the recruitment of Duncan's replacement.

There are no documents establishing a formal search committee and no minutes of any formal committee meetings; nor are there any criteria set out for the candidates that were sought.

Although Collins informed Dr. Agnes Bishop in April 1993 of his intention to leave the hospital at the end of October of that year, it appears that no one—including Collins—took steps to inform the other department and section heads involved in the Pediatric Cardiac Surgery Program of that resignation. Dr. Niels Giddins, the only cardiologist left after Collins, was not aware of Collins's resignation until shortly before Collins's departure.

There was also no formal committee or selection process put into place to find a replacement for Collins, nor was there a formal discussion and assessment made of the potential impact of his resignation on the program so soon after the resignation of Duncan and the other cardiologists. Although Collins gave the HSC six months notice, a permanent replacement had not been found by the time he left. Indeed, by the time the program was suspended in December 1994, a year and a half after his departure, the Children's Hospital had not yet appointed a permanent replacement.

The inability to replace medical staff by the time of their departures may speak to the need to require lengthier notice periods from those HSC staff members whose specialties are in high demand. It may also speak to the need for the hospital to put into place a better method of professional recruitment, particularly for multidisciplinary specialized programs, such as the Pediatric Cardiac Surgery Program. The hospital might have benefited, for example, from engaging the services of a professional recruitment agency.

The details of Odim's appointment, which are outlined in Chapter Five, also indicate the inadequacies of the recruitment process in place at the HSC in 1993. While his credentials appeared to be quite impressive, no one in Winnipeg actually saw him perform a surgical procedure or spoke with anyone at Boston where he had most recently trained, before offering him the position as Chief of Pediatric Cardiac Surgery. The assessment of Odim's operating-room skills appears to have been made largely on the basis of what he told them, where he had trained, what his resume revealed and comments from people who had not observed him in surgery or had had no involvement with him for three years or more. Additionally, little consideration seems to have been given to assessing his ability to work with or develop a surgical team such as was in place in Winnipeg.

Information about Odim was gathered from sources such as personal contacts, word of mouth, interviews and an assessment of paper credentials. These sources can be useful. However, when they comprise almost all the information that is used in coming to a decision as to whether or not to hire an important individual such as a surgeon, they can prove to be ineffective in determining the individual's appropriateness in a number of important areas.

The prime area, obviously, is that of surgical ability. It seems logical to think that when hiring a surgeon, one of the most important areas to investigate is that of the individual's surgical skills and ability. One can properly assume that any trained surgeon has been certified as being capable of performing the surgical procedures associated with the field of specialty for which he or she is being hired. However, such certification does not provide information on the level of skill and ability that the person brings to the position. That can best be determined by observing the candidate while he or she actually performs surgery and by interviewing those who have recently observed the candidate in surgery and have the capabilities themselves to make judgments about the level of skill of the candidate. Those at the HSC responsible for recruiting Odim did none of those things.

Had they consulted with individuals such as Dr. John Mayer, who had supervised Odim during his most recent medical training in Boston, they would have learned that, in his view, Odim was not ready for the position he undertook in Winnipeg. Armed with that knowledge, they might have reconsidered hiring him, or at the very least, been able to put into place measures to monitor and assist Odim, as well as ensure that his lack of experience and need for assistance in some technical areas did not compromise patient care.

All of this speaks to the need for the HSC to revamp the approach it takes to the recruitment and hiring of senior or specialized medical professionals such as surgeons.

RECOMMENDATION

It is recommended that: The HSC establish a medical staff recruitment process for senior or specialized positions within the hospital that has as its main priority the creation of a mechanism that results in the best possible candidate being hired or appointed. The process should include these elements:

> **Before the recruitment of a specialized surgeon to a staff position, personnel in related fields, such as nursing, anaesthesia and perfusion, should have input into the criteria developed for the position.**
>
> **The process should be time-sensitive, and include a provision that requires that those holding senior or specialized positions within the hospital give a reasonable amount of notice to the hospital before leaving, to enable the hospital to seek and hire replacements.**
>
> **The recruitment and hiring process should be overseen by a formal search committee, consisting of the head of the department doing the recruitment and such other individuals as have a related medical or administrative interest in the appointment. This should include nurses. In addition, the search committee should include members with expertise and experience in professional recruitment and hiring.**
>
> **Where there is a limited pool of experienced and/or trained candidates capable of filling the position, the hospital should consider engaging the services of a personnel recruitment agency specializing in the field of professional staff recruitment.**
>
> **When hiring an individual with specialized surgical skills, the department head should ensure that the candidate is observed while performing surgery before a final assessment is made.**
>
> **One of the important criteria for the hiring of a surgeon must be the ability to work well in a team setting and a demonstrated understanding of surgical team concepts.**

THE COMPENSATION PAID TO PEDIATRIC CARDIAC SURGEONS

- Finding

  The manner in which pediatric cardiac surgeons are financially compensated in Manitoba is not satisfactory.

The evidence suggests that one of the issues that encouraged Duncan to leave Manitoba related to the manner by which pediatric cardiac surgeons are compensated financially. As well, this was an issue when Dr. Odim was being recruited, and if not addressed, will continue to present an issue for the future recruitment of pediatric cardiac surgeons.

For a variety of reasons, the global compensation available to pediatric cardiac surgeons in Manitoba is considerably less than that available to adult cardiac surgeons. This results from lower caseloads and lower surgical fees for procedures that are more complex and take longer than adult procedures. This disparity is in large measure based on historic circumstances that no longer apply. Unless the schedule is amended, it will be difficult to attract and retain experienced pediatric cardiac surgeons to this province.

RECOMMENDATION

It is recommended that: The Manitoba government and the Manitoba Medical Association adjust the Manitoba doctors' fee schedule to allow for the payment of compensation to pediatric cardiac surgeons that does not stand in the way of the effective recruiting of, and maintenance of, pediatric cardiac surgeons in Manitoba. The fee schedule should reflect the fact that pediatric cardiac surgeons are as highly trained as adult cardiac surgeons; that because of a lower case load, pediatric cardiac surgeons will perform fewer operations than adult cardiac surgeons; and that the operations that pediatric cardiac surgeons perform will be just as, if not more, complex than adult cardiac operations.

PROBLEMS WITHIN THE PEDIATRIC CARDIAC SURGERY PROGRAM

UNCLEAR LINES OF AUTHORITY

The responsibility of department heads

- Finding

  The evidence establishes that the ultimate responsibility for the Pediatric Cardiac Surgery Program at the HSC was jointly held by the head of the Department of Surgery and the head of the Department of Pediatrics.

- Finding

  The evidence establishes that the lines of authority and responsibility for the Pediatric Cardiac Surgery Program were unclear and confusing to hospital staff during 1994.

The heads of the Department of Surgery and the Department of Pediatrics had overall responsibility for ensuring that the program was providing an appropriate level of service. Their joint agreement was needed for a reduction in service in May and a suspension of the service in December. For the purposes of this report, the persons who held those positions throughout 1994 were:

1. Dr. Robert Blanchard—head of Surgery throughout 1994;
2. Dr. Agnes Bishop—head of Pediatrics until June 1;
3. A variety of persons who held the position of acting head of Pediatrics until September 15;
4. Dr. Brian Postl—head of Pediatrics from September 15.

There was considerable confusion among the staff in the program as to who had immediate responsibility for taking action with respect to their concerns. That confusion was in part due to the fact that the Pediatric Cardiac Surgery Program was a multidisciplinary program within which medical professionals from a variety of departments (Nursing, Perfusion, Surgery, Cardiology, Anaesthesia, Pediatrics, Intensive Care, Neonatology and Pathology) worked on cases in a joint endeavour. This created confusion when it came to determining who had overall responsibility for the entire program, or if those who did have such responsibility were also responsible for specific professionals. This was the case with regard to determining who was responsible for monitoring the performance of the surgeon.

The matter was exacerbated by the fact that, historically, the medical director of the Variety Children's Heart Centre had provided day-to-day management and monitoring of the surgical aspect of the program. This was despite the fact that the surgeon was formally responsible to the section head of Cardiovascular Thoracic Surgery, a position held by Dr. Helmet Unruh on an acting basis. In addition, many hospital staff believed that Dr. Nathan Wiseman, the head of Pediatric Surgery had some responsibility for monitoring the Pediatric Cardiac Surgery Program by virtue of his title. He did, in fact, have very little such authority.

It appears that Dr. Helmut Unruh, the acting section head of CVT Surgery, assumed that Giddins, as Collins's interim replacement, would take over Collins's role in monitoring the Pediatric Cardiac Surgery Program's outcomes. This assumption was neither correct nor appropriate. When Giddins replaced Collins as the head of the VCHC, he did not approach the position in the same manner as Collins had.

Additionally, Unruh and Blanchard should have been involved enough with the Pediatric Cardiac Surgery Program to have recognized the staffing problems the program faced in 1994. They ought to have spoken directly to Giddins about whether or not their expectation was reasonable that Giddins would monitor surgical outcomes.

RECOMMENDATIONS

It is recommended that: If a Pediatric Cardiac Surgery Program is re-established at the HSC, it have clear written lines of authority and responsibility. Efforts must be made to ensure that program members understand these lines of authority. This is of particular importance in a multidisciplinary program.

It is recommended that: If a Pediatric Cardiac Surgery Program is restarted at the HSC, overall supervision for the program should be the responsibility of a single Department Head—logically the head of Pediatrics. The head of Pediatrics can more easily supervise a program that has as its focus pediatric cases. Staff providing service to any revamped Pediatric Cardiac Surgery Program should be primarily assigned to the program and be accountable to the head of Pediatrics through their appropriate department head or line manager for their performance. In particular, the head of Pediatrics should also have responsibility for monitoring the surgical performance of the pediatric cardiac surgeon through the assistance of the head of Pediatric Surgery and the head of Pediatric Cardiology. The head of Pediatrics should ensure that the surgeon, the head of Pediatric Cardiology and the head of Pediatric Anaesthesia have a plan to phase in the surgical program. In addition, the program should be monitored closely, with regular reports going to the head of Pediatrics.

The responsibility of Dr. Jonah Odim and Dr. Niels Giddins for the events of 1994

- Finding

  The evidence suggests that neither Dr. Odim nor Dr. Giddins carried out their responsibilities to monitor and respond suitably to the poor surgical results in the program.

While the department heads had ultimate responsibility for the program, it was the responsibility of the pediatric cardiac surgeon, Dr. Jonah Odim, and the acting medical director of the Variety Children's Heart Centre, Dr. Niels Giddins, to ensure on a day-to-day basis that the program was providing an appropriate level of care.

Additionally, as the referring cardiologist, Giddins, regardless of his role at the Variety Children's Heart Centre, had an additional responsibility for monitoring the surgical outcomes of the cases he referred to Odim.

It is noted as well, that Giddins not only referred patients to Odim, he reassured parents of those patients that Odim was capable of performing any and all of the procedures required for his patients. Therefore he had a responsibility to ensure that the assurances he was giving were justified.

As the chief of service, Odim also had a responsibility to ensure that the program did not undertake cases that were beyond his and the program's ability and experience, to monitor results and ensure the orderly development of the surgical team.

MISUSING THE CONCEPT OF A 'LEARNING CURVE'

- Finding

  The evidence suggests that the acceptance of a learning curve muted the degree of concern that Drs. Odim, Giddins and Wiseman should have had when surgical nurses and anaesthetists voiced concerns about surgical results.

The question of a 'learning curve' needs to be placed into a proper context.

Neither Blanchard nor Bishop (the department heads responsible for the program at the relevant time), the cardiologist nor the surgeon gave appropriate consideration to the fact that junior surgeons (such as Odim) and newly established (or re-established) surgical teams experience a learning curve. This learning curve is a recognized fact. Indeed, it was precisely because of the concept of a learning curve that many witnesses expressed a concern that the Pediatric Cardiac Surgery Program at the Children's Hospital was not able to perform enough operations to allow team members to establish and maintain their skills at a high enough level.

To that extent, there is validity to the consideration of a learning curve for individuals and teams. However, the concept of a learning curve can be abused. There should be no allowance for a learning curve where patient safety is concerned or when analysing results of surgery. While witnesses before this Inquest said that they recognized that a learning curve has no place in determining the acceptability of poor surgical results, there was a noted tendency on the part of some, in defending the events of 1994, to point to what they considered similar 'results' at the start of Dr. Kim Duncan's career in Winnipeg. This was apparently used as a rationale for believing that there was no need to be alarmed about what was occurring in the Pediatric Cardiac Surgery Program in Winnipeg in the spring or fall of 1994. That was simply not an appropriate use of the concept of a learning curve.

The evidence does establish that surgeons and surgical teams have the potential to have higher morbidity and mortality rates in the early stages of their development. These rates are likely to be higher if the program in which they are functioning does not go through a carefully planned and initiated start-up, if it is not properly and closely monitored and if steps are not taken to identify and resolve problems and improve performance. That fact should have caused those in charge of the program to have taken two major steps before the start-up of the program in 1994.

First, an effort should have been made to ensure that an experienced person was in a position of authority in the program to provide guidance with respect to start-up issues that the program was inevitably going to face.

Secondly, those in charge of the program ought to have been careful to ensure that the new surgeon and the restarted program were closely monitored at least throughout the first year. Initial patient selection ought to have been restricted to those cases that promised the best results during the period of time that individual and team experience was gained. The evidence suggests that, unfortunately, few steps were taken to ensure that the program did not take on cases that were beyond the capabilities of either the surgeon or the team as a whole throughout the year. Those in charge of the program acted on the basis that poor surgical results would simply improve over time. That was simply not appropriate.

Blanchard and Bishop, the department heads responsible for the program at the relevant time, Giddins, the cardiologist, and Odim, the pediatric cardiac surgeon, all bear some responsibility in that they failed, individually and collectively, to ensure that the program was restarted on a carefully phased basis.

ADMINISTRATIVE ISSUES

- Finding

The evidence suggests that Drs. Blanchard and Bishop, the department heads responsible for the program at the relevant time, did not address the underlying issues that led to the depar-

ture of Collins and Duncan. Instead, the program was placed in the hands of a relatively inexperienced cardiologist and an even more junior surgeon who had just completed his training.

Two key members of the program's medical staff, Dr. George Collins and Dr. Kim Duncan, resigned from the Variety Children's Heart Centre in 1993, in part, because they believed the centre was not receiving sufficient support from the HSC. While the lack of support they mentioned was partially related to finances, the issue seems to have been related primarily to whether or not the hospital was prepared to support the program in a manner that allowed it to meet the objectives and standards that both Duncan and Collins had set for it.

■ Finding

The evidence suggests that Drs. Blanchard and Bishop failed to recognize that, in light of the significant changes in personnel at the Variety Children's Heart Centre, the lack of experience of the new leadership of the Pediatric Cardiac Surgery Program, and the fact that the cardiologists who had left the program in the previous year and a half had not yet been replaced, the program would require close supervision and monitoring in early 1994.

It would appear that the budgetary and administrative changes undertaken at the hospital during 1993–94 were a significant distraction for the department heads and other supervisory staff. Given those demands during this period, it is conceivable that the department heads did not have the time to provide the necessary leadership for a program that was being restarted. If that was so, Blanchard and Bishop should have recognized that and should have considered delaying the program's restart.

■ Finding

The evidence suggests that Drs. Blanchard and Bishop furthermore did not prepare for or have in place a proper orientation for either a new surgeon or a new director of the VCHC. Giddins was assigned interim responsibility for the position vacated by Collins, but there is no evidence that he was prepared for the duties he was assigned.

■ Finding

The evidence suggests that Drs. Blanchard and Bishop, along with Giddins, also did not ensure that there was either formal or informal mentoring of Odim upon his arrival at the HSC. In the case of a young surgeon in his first appointment following his residency, more careful consideration ought to have been given to the fact that he was facing an entirely different experience from what he had faced as a surgical resident.

■ Finding

The evidence suggests that Drs. Bishop, Blanchard and Giddins also did not ensure that anyone was assigned responsibility or took responsibility for building and mentoring the Pediatric Cardiac Surgery team as a whole in the early part of 1994. Without this leadership, the problems that arose in the early operations rapidly led to unresolved—and, in the end, unresolvable—conflicts.

As a result of the lack of appropriate orientation and mentoring, the program was plagued throughout 1994 with a variety of very serious problems. HSC operating-room and ICU staff were not properly prepared for Odim's particular approach to surgery and post-operative care, while Odim often made assumptions based on his limited experience at other institutions. Examples are numerous and are found in the preceding chapters. These problems may, in fact, have compromised patient care.

- Finding

  The evidence suggests that Drs. Bishop, Blanchard, Giddins and Odim did not give sufficient consideration both to Odim's lack of experience and to the level of team development.

- Finding

  The evidence suggests that the lack of supervision and the lack of a phased start-up plan meant that the Pediatric Cardiac Surgery Program was marked by poor case selection in 1994 and that the program undertook cases that were beyond the skill and experience of the surgeon and the team.

- Finding

  The evidence suggests that the cardiologist and the surgeon did not take appropriate steps to establish and maintain open and ongoing lines of communication with other related medical services in the hospital, such as nursing and anaesthesia.

Additionally, one of the factors that increased team dysfunction was the surgeon's use of techniques and approaches with which other team members were not familiar and for which the surgeon did not prepare them. The surgeon seems to have erroneously assumed that everyone knew what he was talking about. In some cases there was a lack of sufficient consultation and briefing before the team undertook specific, complicated procedures. For example, it would appear that the neonatal intensive care unit staff were not sufficiently briefed and prepared by the surgeon, or the cardiologist, for the patients undergoing Norwood procedures.

RECOMMENDATIONS

It is recommended that: The Health Sciences Centre develop protocols for providing orientation and support to all new staff and staff moving into new positions. This should be done even when the appointment is to an Acting position.

It is recommended that: Any re-established Pediatric Cardiac Surgery Program involve all units that would be affected by the program in the development of appropriate protocols. Such protocols should include a requirement that the entire team, including those individuals responsible for post-operative care, be fully prepared before the program moves to higher-risk cases or new procedures.

INAPPROPRIATE STAFFING LEVELS

Small surgical units must always struggle to find a balance with staffing issues. The team members must not be overworked, thereby putting patient care at risk. At the same time, each team member must be involved in a sufficient number of cases to maintain an appropriate skill level. There are no hard and fast rules on these issues. The evidence suggests that in 1994 staffing levels were stretched throughout the HSC. However, staffing issues in Cardiology, Surgery, Anaesthesa and Pathology proved to be of particular significance.

- **Finding**
  The evidence suggests that Drs. Blanchard and Bishop, the department heads responsible for the program at the relevant time, appear to have failed to recognize fully the implications of only one cardiologist being at the Variety Children's Heart Centre for most of 1994. Steps should have been taken to limit the number of patients seen at the centre, on the basis of Giddins's workload alone.
- **Finding**
  The evidence suggests that the fact that, throughout the existence of this program, there was only one surgeon who was on constant call, also placed a high degree of pressure on the surgeon.
- **Finding**
  The evidence suggests that shortages in the Department of Pathology also contributed to the fact that autopsy reports were not completed in a timely manner.
- **Finding**
  The evidence suggests that an appropriate balance had not been struck between the number of anaesthetists providing anaesthetic care to the program and the number of cases in which each anaesthetist participated.

Evidence was presented to the Inquest that, after spending all night at the bedside of a patient, Duncan was asked by Collins not to undertake a surgical procedure the next morning. On the other hand, there was evidence that Odim went into the operating room to perform a surgical procedure, on very little sleep, after spending the entire night in the ICU.

In contrast, while there were issues relating to staff shortages, there was also an issue with regard to whether there were too many anaesthetists providing service to the program. While there was no evidence presented to this Inquest to suggest that care suffered as a result, legitimate questions were raised throughout 1994 about the number of anaesthetists providing coverage to the Pediatric Cardiac Surgery Program.

The concept of the ability to develop and maintain skill levels is the same for an anaesthetist as for a surgeon, and for that reason, the number of anaesthetists providing coverage for the program should relate to the number of cases available. Williams and Roy, for example, said that the ideal number of anaesthetists should be between two and three anaesthetists for a program the size of Winnipeg.

RECOMMENDATIONS

It is recommended that: Any restart of the Pediatric Cardiac Surgery Program be initiated only after the relevant department heads jointly review staffing levels and assure themselves that they are appropriate to avoid overwork and fatigue and maintain appropriate skill levels. This applies to every discipline involved in the program.

More specifically:

Any restart of the Pediatric Cardiac Surgery Program be initiated only at a time when pediatric cardiology is staffed appropriately.

If the number of cardiologists in the Pediatric Cardiac Surgery Program is reduced following a restart, the program should reduce the level of service it provides.

Any new Pediatric Cardiac Surgery Program have provisions for relief for the pediatric cardiac surgeon. This could involve protocols for referral of patients out of province or arrangements to bring other surgeons into Manitoba.

The Department of Surgery for the HSC establish guidelines and protocols for surgeons that help in the decision as to when to operate if fatigued: for example, after being on call. These guidelines and protocols could be similar to those used by anaesthetists.

The Department of Pathology be properly staffed so as to be able to comply with reasonable guidelines for the completion of autopsies and autopsy reports as set out later in this chapter.

The Department of Anaesthesia ensure that the program has an appropriate number of anaesthetists. This number would have to take into account the need for anaesthetists to be involved in a sufficient number of cases to enable them to obtain a requisite level of experience, as well as ensuring that they are able to provide appropriate coverage for all cases.

TREATMENT OF NURSES

- Finding

The evidence suggests that because nursing occupied a subservient position within the HSC structure, issues raised by nurses were not always treated appropriately.

Throughout 1994, the experiences and observations of the nursing staff involved in this program led them to voice serious and legitimate concerns. The nurses, however, were never treated as full and equal members of the surgical program, despite the fact that this was the stated intent of the administrative changes that the program underwent in June 1994. Intensive care unit nurses, for example, were never properly involved in the review team that assessed the program during 1994, and nurses were not properly involved in the Williams and Roy Review. The concerns expressed by some of the cardiac surgical nurses were dismissed as stemming from an inability to deal emotionally with the deaths of some of the patients. As well, any concerns over medical issues that the nurses expressed were rejected as not having any proper basis, clearly stemming from the view that the nurses did not have the proper training and experience to hold or express such a view. In addition, while HSC doctors had a representative on the hospital's board of directors, nurses did not.

Historically, the role of nurses has been subordinate to that of doctors in our health-care system. While they are no long explicitly told to see and be silent, it is clear that legitimate warnings and concerns raised by nurses were not always treated with the same respect or seriousness as those raised by doctors. There are many reasons for this, but the attempted silencing of members of the nursing profession, and the failure to accept the legitimacy of their concerns, meant that serious problems in the pediatric cardiac surgery program were not recognized or addressed in a timely manner. As a result, patient care was compromised.

■ Finding

The evidence suggests that nurses were not allowed to play a role in planning the February 1994 restart of the Pediatric Cardiac Surgery program, even though they formed an essential element of that program.

The concerns expressed by the PICU and the NICU nurses over the types of procedures that were to be carried out in the intensive care units were not addressed in a timely manner. In a number of cases it appears that the concerns of the operating room nurses over the nature of the deaths that occurred and with the mortality rate were interpreted as an inability to cope with the unfortunate, unavoidable death of a child. There was an implication that the nurses lacked a vision of the larger picture.

When the hospital was reorganized in the summer of 1994, the position of Vice-President (Nursing) was eliminated, although a commitment was made by the President of the hospital that there would always be one vice-president with a nursing background. (While the medical vice-presidency was also eliminated, HSC doctors continued to have direct representation on the HSC board). The restructuring that took place in 1994 also led to the creation of the position of unit manager, to replace the previous position of head nurse. While there were a number of benefits to this structure, creation of the new position led to a situation where nurses could theoretically be reporting to non-nurses. (While head nurses had to be nurses, this is not the case with unit managers.)

Finally, the evidence suggests that despite its stated intent, the hospital reorganization of 1994 implicitly devalued nurses, since it appears to have been driven by a concern to cut costs primarily by reducing staff, the bulk of whom ended up being nursing staff.

Throughout 1994 the nurses made proper and appropriate use of existing channels to voice their concerns. For a variety of reasons—some personal, some institutional—their concerns were not attended to. Indeed, the reception they were given led some nurses to silence themselves. It also left them frustrated and distraught. Many paid a heavy emotional price. By the time the program ended, at least one nurse was on the verge of taking her concerns outside the hospital, at great risk to her position and career.

It is necessary to put in place structures that ensure that all staff can make their concerns known without fear of reprisal. It is also important to ensure that the structure of the HSC be adjusted to ensure that the position of nursing does not continue to be a subservient one.

RECOMMENDATIONS

It is recommended that: The HSC restructure its Nursing Council to allow nurses to select its membership and to give it responsibility for nursing issues within the hospital. The Nursing Council should have representation on the hospital's governing body and be responsible for monitoring, evaluating, and making recommendations pertaining to the nursing profession within the hospital and

for nursing care. The Council should also serve as a vehicle through which nurses could report incidents, issues, and concerns without risk of professional reprisal.

It is recommended that: The HSC establish a clear policy on how staff is to report concerns about risks for patients. This policy must ensure that there is no risk to the person who is making the report. It should be clear to every staff member to whom they are to present such reports.

It is recommended that: The Province of Manitoba consider passing 'whistle blowing' legislation to protect nurses and other professionals from reprisals stemming from their disclosure of information arising from a legitimately and reasonably held concern over the medical treatment of patients.

TREATMENT OF THE FAMILIES

The families of the children who died in 1994 put their faith and the lives of their children into the hands of our health-care system. As indicated at the outset of this chapter, the evidence suggests that these children did not always receive the standard of care that their parents had every right to expect. The preceding findings and recommendations have addressed the reasons why the system failed to provide an appropriate level of care. However, there are a number of findings that must be made about the way parents were and were not informed about matters that were of the utmost importance to them.

THE ISSUE OF INFORMED CONSENT

- Finding

The evidence suggests that the parents of the children involved in these cases were not as fully informed as they were entitled to be when asked to give consent to surgery on their children.

Patients and family members granting consent on behalf of a patient are entitled to know the risks involved, before they give their consent to surgery. However, there was clear disagreement over the sort of information that must be shared.

The experience of the surgeon and the team

A number of the medical witnesses felt that declaring one's medical experience is not a requirement for informed consent, while many of the parents felt strongly that they should have been provided with more information about the program and about the surgeon's experience.

Many hospital staff seemed to feel that it was appropriate to describe the surgeon as highly trained, or 'one of the best', and to state that the Winnipeg program was 'as capable as anywhere else'. Yet they also felt it would have been inappropriate to tell the families that Odim had not performed any of the procedures he proposed in 1994 without supervision. How one could feel free to do the former while not feeling obligated to do the latter is a matter of some concern.

Some witnesses felt that the patient or parent is owed the truth if a question about previous experience is asked, but that a doctor can remain silent on the same point if the patient or parent does not ask. While the obligation to tell the truth is obvious, it seems illogical that some would see the obligation to be truthful as not encompassing an obligation to disclose a relevant fact.

While it might not be necessary to disclose a surgeon's abundant experience at performing a particular procedure, a surgeon's lack of experience is clearly a fact that is relevant to the question of whether or not someone would be willing to entrust his life, or the life of his or her child, to that surgeon. For that reason alone, such information ought to have been disclosed without prompting.

Information about surgical risk

Furthermore, the risk factors that were cited to parents for the procedures undertaken by Odim in 1994 were not based on the facts of the situations that the children actually faced in Winnipeg.

In many cases the indications of risk that were given to the parents were reflective of profession-wide risk, rather than the level of risk for the procedure at the HSC. Information such as the relative inexperience of the surgeon, and the fact that he would be performing the procedure in an unsupervised setting for the first time in his career, was not factored into the risk assessment shared with the families. This information should have been included when determining what risk level to advise the parents was associated with the operation on their child.

All the available data clearly suggest that there is a risk factor attached to a surgeon's experience. While that risk factor diminishes with experience, the fact that it is clearly higher with inexperience ought to have been disclosed to the parents, along with an indication as to what was applicable with Odim. Additionally, the state of experience and level of functioning of the surgical team was not, as it ought to have been, factored into the assessment of risk.

Information about the May 17 withdrawal of services by the anaesthetists

All parents whose children underwent operations after May 17, 1994, should have been informed about the anaesthetists' withdrawal of service on that date. As well, parents were entitled to be informed of the decision to perform only low-risk procedures thereafter, and the decision to resume full service in September 1994.

Information about the Williams and Roy Report and the February 1995 suspension of the program

Parents also should have been made aware of the Williams and Roy report and should have been allowed to read it. Additionally, parents should have been contacted and informed of the decision to suspend the program in February 1995, before that decision was made public.

RECOMMENDATION

It is recommended that: The Department of Health of the Manitoba Government prepare a patient's rights handbook that, among other things, deals with the issue of informed consent. That handbook should clearly set out that a patient and a parent acting on behalf of a minor have a number of rights, including, but not limited to:

- The right to be fully informed before giving consent to medical treatment;
- The right to information about a surgeon's experience in performing a particular procedure, as well as the experience of the hospital and/or surgical team;
- The right to a second opinion;
- The right to an out-of-province referral in certain circumstances, including where the patient or parent chooses to have a procedure performed by a surgeon or institution with more appropriate experience and where the surgeon or institution in Manitoba lacks the same experience; and
- The right to have an out-of-province surgeon perform the procedure in Manitoba, provided that there is a surgeon willing and able to do the procedure here.

It is recommended that: The Department of Health direct Manitoba hospitals to require that, as part of their obligation to obtain informed consent from a patient, hospitals have a positive obligation to provide to a patient, or a parent on behalf of a minor, information about:

- The right to information about a surgeon's experience in performing a particular procedure as well as the experience of the hospital and/or surgical team;
- The right to a second opinion;
- The right to an out-of-province referral in certain circumstances, including where the patient or parent chooses to have a procedure performed by a surgeon or institution with more appropriate experience and where the surgeon or institution in Manitoba lacks the same experience; and
- The right to have an out-of-province surgeon perform the procedure in Manitoba, provided that there is a surgeon willing and able to do the procedure here.

It is recommended that: The HSC review its policies on consent and communication with families. All information that is germane to a child's care or to decisions that must be made about a child's care should be provided to those from whom consent is being obtained. In particular, the policy on consent must make it clear that the medical staff treating a patient must be forthright and truthful in disclosing all relevant information to the patient or representative before the procedure in question. The fact that a surgeon has not performed a particular surgical procedure on his or her own in an unsupervised setting in the past must be disclosed.

FUNDING FOR THE FAMILIES

- Finding

The evidence suggests that the families involved in this Inquest were hampered throughout the hearings by the burden of the costs associated with having legal counsel present throughout.

An important issue that arose almost from the outset of these proceedings had to do with the question of funding for legal counsel for the families involved in these proceedings.

The families of the 12 children who died in 1994 had compelling reasons to choose to follow and participate in the proceedings of this Inquest. However, the length of the proceedings and their complexity would have effectively barred all but the wealthiest of families from participating. The struggle of the families for financial assistance for their legal costs as the proceedings wore on was mentioned from time to time, although no formal assistance was sought from me. However, from the information available, it is unclear if all or only a portion of the legal costs of the families who participated have actually been covered. I believe that the families are entitled to have all their legal costs associated with this Inquest paid.

The role of all counsel for the families was of fundamental importance in these proceedings. While both counsel for the Inquest performed their tasks admirably, their role was not that of advocate for the families, but to bring forward the evidence as best they could. Given the active role of counsel for the other parties under scrutiny, having counsel whose sole responsibility was that of advocating for the families was essential for a fair and proper proceeding.

In this case the families actively pursued the matter with the government of the day and were successful (in part at least) in persuading government to pay for their legal costs. However, it seems unfair for families to have to take steps to persuade the government to provide them with financial assistance for legal costs on a case-by-case basis. Families that are best able to develop and marshal private or public support stand in a potentially more favourable position than do those whose political contacts or influence is lesser.

It is not unusual for Inquest proceedings to inquire into the conduct or decisions of a government department or official. In such a case, for the government to decide whether or not to pay for the legal costs of counsel for the deceased's family, without the family knowing on what basis such assistance will or will not be provided, can lead to the appearance of unfairness. Therefore some guidelines for such assistance should be provided.

RECOMMENDATIONS

It is recommended that: The Government of Manitoba establish a policy for the payment for counsel for families granted standing at inquests, taking into account the following factors:

1. **The length of the proceedings.**
2. **The complexity of the issues.**
3. **Whether or not the costs of family involvement in the proceedings would be prohibitive to the applicant.**
4. **Whether or not the presiding judge so recommends on application by the family.**

It is recommended that: The Government of Manitoba pay the entire legal costs of the families involved in these proceedings.

The amount of legal costs to be provided to the families involved in these proceedings be referred to an independent fact finder appointed by the Manitoba government and agreed to by the families. The fact finder shall investigate and make a report to the provincial government on whether or not the families should receive any additional financial assistance for legal costs beyond that which has already been provided. In determining what amount should be provided, the fact finder should have regard to the criteria mentioned above, as well as any amounts that have actually been paid. The rates paid to outside counsel retained by the Government should be used as a guideline.

COMPENSATION

In their presentations to this Inquest, counsel for some of the families have asked me to make a recommendation as to whether or not the families are entitled to financial compensation for the deaths of their children. It should be clear to any reader of this report that families did not always receive all the information that should have been provided to them and that their children's care did not at all times meet an acceptable standard. I have made numerous recommendations based on these findings.

However, I have concluded that I am unable to make any recommendation regarding such compensation. As noted in Chapter One of this report, an Inquest cannot make findings of culpability. For me to make a recommendation as to the question of financial compensation for the death of a person who is the subject of the Inquest would likely contravene my obligation not to make a finding of culpability. Secondly, it would appear that the families that have asked for compensation have already started civil proceedings. The question of their entitlement to compensation is best determined in accordance with the rules and laws applicable in those proceedings.

MONITORING OF ISSUES AND PROBLEMS WITHIN AND OUTSIDE THE HSC

MONITORING WITHIN THE HSC

The evidence discussed in Chapters Six through Nine gives rise to the following findings regarding issues of monitoring of the HSC's Pediatric Cardiac Surgery Program in 1994.

- Finding
  The evidence suggests that the formal and informal monitoring of issues at the HSC failed to identify the problems with the Pediatric Cardiac Surgery Program in a timely fashion.

- Finding
  The evidence suggests that Drs. Blanchard and Bishop, the department heads responsible for the program at the relevant time, as well as the cardiologist, and the surgeon, did not adequate-

ly monitor surgical performance and results of the PCS program, on either a case-by-case or collective basis, particularly in the early startup period of 1994.

- **Finding**

  The evidence suggests that Drs. Blanchard and Bishop, the cardiologist and the surgeon also did not appreciate the significance of the poor level of communications and the poor interpersonal relationships between the surgeon and others that very quickly developed, and continued throughout the year.

- **Finding**

  The evidence suggests that Drs. Blanchard and Bishop were slow to respond effectively to concerns that were raised by program staff in the spring of 1994.

- **Finding**

  The evidence suggests that Drs. Bishop, Blanchard, and Craig should have informed their respective vice-presidents, in writing and in detail, of the anaesthetists' withdrawal of services in May 1994.

- **Finding**

  The evidence suggests that the Pediatric Cardiac Surgery Program should not have been allowed to return to full service in September 1994.

- **Finding**

  The evidence suggests that Dr. Odim's membership on the panel of surgeons that reviewed each surgical death for the Children's Hospital Standards Committee had the potential for a serious conflict of interest when the death involved one of Dr. Odim's patients.

As the numerous findings in this section indicate, there was a generally a failure of monitoring of issues and problems at the HSC in 1994.

There was no tracking of common indicators that might point to matters of concern, such as the duration of cardiopulmonary bypass times, the duration of total circulatory arrest times, the volume of blood loss, the number of units of blood and blood components transfused. According to the evidence, there were no plans in place to develop such a database at the time that the program was suspended. While a database was eventually developed, and showed times for such details as cardiopulmonary bypass, total circulatory arrest and cross-clamping, the database provided only a list of details for each individual patient. While data were collected for each child, they were not collected and analysed for patients as a group. As a result, it was not possible to track trends.

Nor was there any attempt to collect data from the Pediatric Cardiac Surgery Program and compare the results of the Winnipeg program with any others, and make some evaluation of the program's performance.

There was no debriefing setting in which members of the surgical team could debate and discuss preoperative issues, intra-operative care (including surgical procedures and post-operative care) and outcomes. The M & M Rounds were mentioned as a possible setting for such discussions, but they dealt with cases long after the operation. (This was usually several weeks after the autopsy had been completed.) In addition, the M & M Rounds were clearly intended as teaching and learning opportunities for staff in the hospital generally and were open to individuals not involved in the case, such as medical students. These rounds were not intended as a forum for a full and frank discussion of the details of each procedure. These factors meant, in the medical culture of the time, that the M & M rounds provided limited opportunity where related concerns, such as communication between personnel, could easily be discussed.

In addition, the medical culture of the HSC unfortunately reflected the concept of the surgeon as the supreme and infallible captain of the ship. This meant that what should have been the collective concern about the team's ability to handle certain cases turned into highly charged conflicts centring on the surgeon. Once framed in that manner, it became difficult to have open discussions or successfully resolve the issues.

Furthermore, despite formal policies, it is clear that the use of incident reports was not an engrained element of the HSC culture. Hospital staff observed many serious and alarming events in 1994. Indeed, many staff members began keeping private accounts of these events. However, only one incident report was filed for the cases under review during the entire year. Problems and complications during operations were often not charted, recorded or reported to the Standards Committee.

The Standards Committee structure that the HSC depended upon was simply not capable of addressing and evaluating important questions in a timely fashion. The Standards Committee process did not, in most instances, begin to review a death until an autopsy had been completed.

Finally, often in 1994, managers ignored pertinent information that was brought to their attention and, at best, simply tolerated the bearers of bad news. Lamentably, the responsibility for dealing with this information was never clearly delineated.

MONITORING OUTSIDE THE HSC

- Finding

The evidence suggests that the Chief Medical Examiner's Office failed to identify the problems with the Pediatric Cardiac Surgery Program in a timely fashion. This is in large measure a result of over-reliance on information provided by the surgeon alone and the fact that, in most cases, the CME's investigation team waited for the final autopsy report. Autopsy results were not available to the Chief Medical Examiner's Office in a timely manner.

The office of the CME did not track surgical deaths by program. As a result the CME's office was not able to identify trends in the Pediatric Cardiac Surgery Program.

The office of the Chief Medical Examiner was not informed of the changes in the Pediatric Cardiac Surgery Program in 1994, particularly the anaesthetists' withdrawal of service on May 17, the slowdown that occurred afterward and the Wiseman Committee review. Since these events were linked to concerns about mortality, it was critical to any review of surgical deaths and, as such, ought to have been communicated to the CME's office.

In these cases, while the Chief Medical Examiner's investigators read the charts and spoke with the surgeon about the patients who fell under the Chief Medical Examiner's jurisdiction, even a cursory discussion with the nurses and the anaesthetists would have revealed significant underlying concerns.

In the autopsies performed in these cases, over-reliance was clearly placed on the information that was obtained from the surgeon. If the information as to what happened during surgery is vital to the conclusions to be drawn by the pathologist, a greater attempt must be made to gather such information from as many of the people involved in the proceeding as possible. To rely exclusively on the one party who might be most responsible for the fatal outcome seems unwise.

The autopsies of the children whose deaths are under review were done in a timely manner; however, the final reports in some cases took months to complete. In none of the CME cases were final reports completed within 30 days of the autopsy as set out in the *Fatality Inquiries Act*. This meant that those responsible for monitoring the program, such as the CME and the Children's Hospital Standards Committee, were not able to use them effectively. The delays were due partially to staffing shortages in the Department of Pathology, as well as to the length of time that it took for all laboratory tests to be completed.

The timelines for the completion of autopsy reports ought to reflect reality as well as change it, because the length of time to obtain these reports seems far too long.

It also is not appropriate to have the autopsies in Chief Medical Examiner's cases involving surgical deaths performed by the staff of the hospital in which the operation took place. The better practice would be to have autopsies in CME cases performed by a pathologist not affiliated with the hospital in order to overcome any appearance of a potential conflict of interest.

Additionally, the HSC's practice of not informing parents that their children's hearts would be retained following autopsies was not appropriate.

RECOMMENDATIONS

It is recommended that: The Office of the Chief Medical Examiner develop a protocol requiring hospitals to inform that Office of significant changes in the delivery of medical services, such as program slowdowns and shutdowns, as well as any hospital-related deaths that cause the hospital to undertake a program review.

It is recommended that: The Office of the Chief Medical Examiner maintain a database of hospital deaths, which would track in-hospital deaths and causes of death on a weekly and monthly basis.

It is recommended that: As part of their investigation into a patient's death, the Chief Medical Examiner's investigators conduct preliminary interviews of nursing and medical staff who had been involved in the patient's care.

It is recommended that: For CME cases the Chief Medical Examiner arrange to have autopsies performed by a pathologist not affiliated with the hospital where the operation has been performed, unless it is unreasonable or impossible to do so due to distance, time or expertise.

It is recommended that: The Chief Medical Examiner develop guidelines for pathologists to follow in obtaining information before performing an autopsy in CME cases. These guidelines should not place over-reliance on anyone whose involvement might have contributed to the death of the patient.

It is recommended that: The Office of the Chief Medical Examiner establish reasonable timelines to complete autopsies, prepare and forward preliminary results and complete the final reports, including the completion of necessary laboratory work.

It is recommended that: The Chief Medical Examiner insist on compliance with reasonable timelines for the preparation and delivery of autopsy results.

It is recommended that: The HSC and other hospitals amend their autopsy consent forms. The forms should make it clear that the hospital might wish to retain organs and other specimens from the bodies of deceased patients. Families should have the option of withholding such consent, while still consenting to the autopsy itself.

HUMAN AND MEDICAL ERROR

In performing its mandate, an inquest has a responsibility to determine if changes are needed in the way that institutions and organizations go about their activities, so as to prevent such deaths from recurring. That requirement calls upon judges who preside at inquests in this province to consider the question of medical error and institutional responsibility. While it does not permit inquest judges to declare on the question of culpability (as has been discussed elsewhere), it does permit judges to identify and discuss individual and institutional error.

ERROR, ACCIDENT AND HUMANITY

Pediatric cardiac surgical procedures are planned and performed by human beings. The hospitals in which those procedures are carried out are designed and built by human beings. They design, manufacture, and maintain all the equipment used in the diagnosis of patients, and in their anaesthetic, surgical and intensive care. Human beings decide if a child will or will not undergo pediatric cardiac surgery. Human beings, as a team, provide the child's pre-operative, intra-operative and post-operative care.

Human beings make errors. We make errors in the design and construction of systems. (A system is defined as a grouping of inter-related components, which interact within a working environment to produce an outcome.) Thus, the health-care system represents everything from patients, personnel, the equipment and the environment within which care is provided, the organizations that provide that care, and the regulatory agencies, such as the government, that legislate or otherwise regulate the provision of health care.

We make errors in the design and construction of technology used in the system, and we make errors when we maintain those technologies. We make errors when we plan and when we execute plans. We make errors when we execute individual tasks that are part of a larger plan. We make errors through ignoring rules, misapplying rules, forgetting to execute part of our plan, and failing to execute plans properly. All errors and problems in a hospital, such as surgical complications, are related to human activity. Error is a human reality.

It is completely appropriate to strive to eliminate error or reduce the frequency at which errors are made. It is, however, unrealistic to believe that human error can be totally eliminated. More importantly, it is impossible to design a system that relies totally on everyone doing the tasks assigned to them properly. Allowances must be made for the possibility that errors will be committed and mechanisms to address that possibility must be put into place.

It is important, therefore, to set out how human error in a medical setting ought to be addressed by the hospital.

DEALING WITH HUMAN ERROR

Error can be handled in two very different ways. One way is to seek out and identify the one who committed the error in order to hold him or her, or the institution that employs the 'culprit', responsible for it. The other way is analyse the error in order to learn from it and to improve things so as to reduce the probability that the error will not be made again.

Blaming

Blaming or holding people responsible and accountable for their actions, such as those types of error which involve violations of existing standards or rules, is a major focus of the court system. The laws of torts, of contracts, child welfare and crime—among others—all focus on the consequences that come to bear, or at least ought to, on the person who commits a legal wrong.

Legal blaming involves a determination of culpability in order for the system to become engaged in the resolution of the matter. Legal blaming, or fault finding, is a normal (indeed, perhaps even necessary) aspect of resolving and addressing those errors that violate rules or standards. Judicial systems exist in part to provide a vehicle by which individuals can address the question of wrongs that are committed against them or their loved ones, in order that they can relieve their feelings of loss, pain and anger. Without a properly functioning judicial system, some have argued that people may surrender to the urge to exact revenge for their loss and pain upon the individual or institution they feel is most responsible.

Learning from human error

However, because inquests are not able to make findings of culpability, the obligation of an inquest ought therefore to be to focus on discussing error in the context of what can be learned from it.

For the same reason, hospitals need to approach the issue of error from a learning perspective, for they have an obligation to provide the best possible care to their patients. If it is discovered that a problem has resulted from human error during the course of treatment, then hospitals ought to be empowered—indeed obligated—to consider such error from the perspective of what can be learned. In particular, efforts should be made to determine how to prevent errors from recurring, by discovering where the flaws lie in the system that contributed to errors being made.

In order to do so, a process must be put into place that emphasizes the need to gather and consider all of the relevant facts in an honest and candid manner, without regard to any individual or institutional consequences that might flow from the errors.

For that to happen, consideration must obviously be given to balancing the issue of confidentiality and protection of informants from liability for describing what happened, with the equally strong need for patients and their families to be informed as to what really happened.

THE INVESTIGATION OF HUMAN ERROR

While humans are responsible for all errors, it is often extremely difficult to determine the underlying reason for a problem or complication. Indeed, it is usually a mistake to try to seek out a single cause of a complication in the belief that eliminating that one cause will result in eliminating all future problems of the same kind. Serious, untoward results come from a series of errors: errors of omission and commission and errors of planning and execution. A death in the operating room might easily result from more than one type of error. Errors of commission might be made by someone who carries out a task incorrectly because of a misunderstood instruction. Errors of omission might include the institution's lack of training to ensure that operating-room personnel analyse and improve communications.

The descriptions of errors in this report are a necessary first step in an analysis of how individuals on their own and those responsible for organizations and regulatory agencies can learn from error. While analysis is required, however, it is often hindered by forces that exist within the medical community. These forces seek to minimize the appearance of errors when they occur. This may arise from the fact that the current culture of medicine reinforces the belief that medical personnel must perform without error. All too often, the making of an error in medicine is equated with a moral failing or is regarded as a sign of ignorance or incompetence. To admit to error, or to imply that a colleague's actions were in error, is to raise serious questions about someone's competence, and hence legitimacy and authority within the health-care system. One of the aims of this Report is to contribute to increasing openness about the existence of human error in the medical community.

One of the reasons why the medical system is able to operate as if doctors, nurses and other health-care workers were flawless is the fact that very few errors actually lead to problems or complications for a patient. In a few cases, the potential negative effect of an error does not actually materialize because the error is made in isolation of any other significant factor that might trigger the development of a problem. In most cases, an error such as failure to comply with a standard operating procedure is caught, either by a safeguard that is built into the system, or by medical personnel (by the person making the error or by someone else). In other cases, the effect of an error on the patient's condition is negligible. But this does not happen in all cases—some errors, in combination with other factors, do lead to some patients developing complications, which may range from minor irritation to death.

HIERARCHY OF THE EFFECTS OF ERRORS

Errors, in and of themselves, are worthy of assessment, regardless of consequences. Although some errors may not have negative consequences, there is, in effect, a hierarchy or evolution of the effects of errors. This hierarchy starts with errors that give rise to simple incidents, which may evolve into more serious events called 'critical incidents', which may then evolve into 'complications' or 'accidents'.

Errors are unplanned events that could, or do, lead to negative consequences. Humans commit errors, not because of any moral failing, but because humans are flawed beings, working in flawed systems that together contribute to the commission of errors.

Errors, coupled with a patient's medical condition and other flaws in the system, can result in an incident. The occurrence of an incident simply implies that the course of care, such as a cardiac operation, did not go as planned or predicted.

Should an incident occur, given the right circumstances, it may then contribute to the development of a 'critical incident'. The transition to critical incident is characterized by the development of the potential for harm to a patient, but not actual harm. This is the threshold point before a complication occurs. Another term for a critical incident is an 'adverse process'.

A critical incident may then further evolve into a complication or 'accident'. (Use of the word 'accident' should not be taken to mean that the problem arose 'accidentally' or by chance.) Only when the outcome of a case is not as planned or predicted, and the patient has suffered some harm, is an accident said to have occurred. Another term used in medicine to describe an accident is an 'adverse outcome'.

Nevertheless, it is important to understand that in medicine, errors only rarely lead to complications and so usually do not get past the 'incident' stage. For that reason, perhaps, incidents and even critical incidents are rarely recorded. When they are recorded they may be dismissed, or not pursued, because they did not produce negative results or consequences. Critical incidents are often termed 'near misses' and the fact that they did not give rise to complications is often ascribed to 'good fortune'. It should be understood however, that the lack of complications (or 'good fortune') ought to have no bearing on the question of whether or not an error occurred. All that the phrase 'good fortune' really means is that those discovering the incident were unable (or unwilling) to determine the reasons for the 'near miss' and acted solely on the basis that the lack of a negative result was enough. Similarly, to dismiss the occurrence of complications as simply 'bad luck' is to forfeit the opportunity to determine some of the underlying contributory factors to the problem.

When investigating a problem with patient care, it is not enough simply to determine 'what' happened: for example, the patient died. Nor is it enough to determine only 'how' the patient died: for example, from being given the 'wrong' drug because of human error. The most important, and often ignored step, is to determine 'why' the patient died and the underlying contributory system and human factors to the making of the error. (Some examples include confusing labelling of the drug, inadequate lighting, two patients with the same name, an over-worked and fatigued doctor, and lack of an assistant.)

Everyone can learn when studying their own and others' errors. Improvements in the system would be made more rapidly, however, if errors, incidents and critical incidents were more closely and systematically examined.

The importance of early reaction to error

One of the facts that clearly arises from these proceedings is that there was a clear lack of a timely and critical examination in the hospital of the events that occurred in the operating room during the surgical procedures that have been the focus of this report.

The M & M Rounds, which were often described in the evidence as a means by which mistakes could be identified and discussed, failed in several other respects. These rounds involved several other people in the hospital over and above the team members involved in the operations. They also did not have the appropriate focus as will be seen later in this discussion. More importantly, the rounds were not scheduled at times that allowed for or required full participation by all team members.

While it is possible that the Wiseman Committee was intended to provide such a process, it failed to do so in several respects, all of which have been discussed in detail elsewhere in this report.

There was also a report issued by the Paediatric Death Review Committee of the College of Physicians and Surgeons that assessed the deaths of these twelve children and which concluded that four of these deaths might have been prevented through better medical management. That review did not occur until long after the events in question. However, that review did not involve the program participants in a team-like setting, nor allow for the sharing of results in a manner that contributed to the improvement of the team's overall ability to perform their tasks or improve their collective and individual abilities to treat their patients better. As well, that review did not consider the errors and 'near misses' that did not have fatal consequences.

Furthermore, the Williams and Roy review in 1995 was not intended as a review of error. It was intended as an overall assessment of the program. There was no attempt by those reviewers to look at each or any of the cases.

What was clearly missing at the HSC in 1994, therefore, was a process that allowed team members to comfortably and collectively assess and evaluate the events that occurred in the operating room in a manner that contributed to improvements in the way that the patients were treated. Because of this deficiency, problems and concerns developed to the point that by the time of the death of the twelfth child, the level of confidence among those within the program was at its lowest. It is safe to say that most members of the team probably felt anxiety over whether or not they could perform even the simplest procedure without complication.

If the hospital is to consider renewing the program or participating in a similar program in a different form, it needs to seriously consider developing a better process for members of surgical teams and programs to learn from the mistakes that they will inevitably make. Even if the hospital does not move toward re-establishing a similar program in the future, a mechanism that focuses members of a surgical team on the process of learning from mistakes would be of benefit to the hospital generally. Therefore, such a mechanism will be discussed.

HUMAN FACTORS ANALYSIS

Where should institutions focus their attention as they work to create mechanisms to identify errors, limit their impact, and prevent their recurrence? Persuasive evidence was presented to the Inquest suggesting that the field of human factors analysis provides some useful tools in making this decision.

Human factors analysis arose out of the study of accidents in the aviation industry. Studies of air disasters suggested that the majority of accidents did not result from technological faults or a lack of technical skills. Instead, the studies suggested that in addition to an underlying flawed system, the contributing factors or triggers for the disaster lay within the area termed human factors. This is the scientific discipline concerned with interactions among humans and other parts of a system in carrying out a purposeful activity. Human factors include leadership, teamwork, communication and decision-making.

These issues have also been identified as critical in medical mishaps. Leadership, teamwork, communication and decision-making are recurring themes in this Report. They are not side issues, not matters of mere personality difference, but central issues. Where these issues were not resolved, they often led to tragic results.

Human factor analysts suggest that the errors, incidents, critical incidents and accidents that arise from human behaviour can best be addressed in a systematic fashion through programs of quality assurance and error and risk management. These programs need to address the behaviour of people who might appear to perform at less than an optimal level. However, more importantly, these programs must address what are termed 'systemic issues', that is, problems that lie within the whole of the hospital or even the health care system itself.

A NEW APPROACH TO THE HANDLING OF MEDICAL ERROR AT THE HSC

As noted in Chapter Four, the HSC was formally committed to the concept of quality assurance. Whether or not it was able to achieve its commitment is a matter that was a significant part of the investigative review undertaken into these 12 deaths.

It is clear from the findings set out in this chapter, that the current reliance on line management, incident reports, and the Standards Committee structure at the Health Sciences Centre was just not sufficient to prevent the events that led to the deaths of these children. While the safeguards that the hospital did deploy must be left in place, they must also be augmented. The HSC must develop an institutional culture in which information about safety hazards is actively sought, messengers are trained to gather and transmit such information, and responsibility for dealing with that information is shared by all. This will require new approaches to quality assurance, risk management and team performance.

Dr. Jan Davies[1] prepared a detailed report on these topics for this Inquest. Her report outlines how modern health-care institutions are incorporating new approaches to quality assurance, risk management and team performance into their operations. The evidence presented to this Inquest indicates that the HSC must adopt and adapt these approaches. The following sections outline a number of key elements in a new approach to the handling of medical error at the HSC.

The benefits of these approaches include:

- For patients (and their families): an improvement in safety of the care delivered, as measured and demonstrated through the review of complications, such as death or injury;

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[1] Dr. Jan Davies was, at the time of her testimony, a professor of anaesthesia in the Faculty of Medicine at the University of Calgary and a member of the medical staff of the Calgary Regional Health Authority hospitals. A 1975 graduate of the University of Calgary's Faculty of Medicine, Davies interned at Dalhousie University in Halifax, Nova Scotia, from 1975 to 1976. She completed her anaesthetic training there, between 1976 and 1980, during part of which time she was also a research fellow in the Departments of Physiology and Biophysics and Anaesthesia. She was appointed a member of the active anaesthesia staff of the Victoria General and Camp Hill Hospitals in Halifax and a fellow in the Department of Anaesthesia at Dalhousie University in 1980. In 1981 she was appointed an assistant professor and then in 1985 an associate professor at the University of Calgary. Davies was qualified to give expert evidence in medical error, human factors, quality assurance and surgical team dynamics. Her expertise was established as a result of her extensive study in the area, as well as her numerous publications, since the early 1980s.

- For health-care workers: an improvement in morale, in part because of improved patient outcome and in part because of an improvement in the process of the delivery of care. Teams that communicate and work together more effectively will also work more efficiently;
- For the organization: an improvement in efficiency. This can be measured against the use of both physical and fiscal resources.

Quality Assurance

Quality Assurance (QA) differs from the traditional method of establishing a particular standard of care as acceptable, or unacceptable. The traditional method often serves only to point the finger at one individual whose performance may not have been optimal. QA is also unlike quality assessment, which seeks only to determine the quality of a service. QA programs go beyond simply ensuring that quality care is being provided. Rather, they seek to improve quality and stress the need to identify problems, develop and implement solutions and monitor results to ensure that solutions work. They also need to ensure that they do not introduce new problems through a comprehensive method which involves working from the solution back to the original problem. This is sometimes referred to as 'closing the loop'.

The primary goal of any QA program should be to provide both excellent patient care and optimal working conditions for the providers of that care. Although health-care workers may need to continue to work under pressure (e.g., during natural or environmental crises) it should be kept in mind that the results of that care will suffer. Thus, quality assurance should also contribute to the development of optimal workplace conditions.

QA programs emphasize the importance of monitoring systemic performance and should be guided by information about the performance of the team, the organization and medicine in general. Data should include problems from everyday life, results concerning the actions of the team and team members' attitudes, the operation and culture of the organization and new trends in the provision of health care. A quality assurance program will therefore require a quantitative database to be effective. Measurement of outcome, however, particularly mortality, may not be sensitive enough to show that there is systemic dysfunction. For this reason, emphasis must be placed on evaluating even those processes of care that might have led, but did not lead, to a complication.

Use should be made of ongoing, episodic and focused measurements and evaluations. In the period under consideration, funding cutbacks led to a decrease in computerized record keeping of the Department of Anaesthesia's data collection program. This should not be allowed to happen again. When quality assurance processes are eliminated or suspended because of financial considerations, there cannot be any assurance that health care may not also be compromised. That is what the compilation and evaluation of such data are intended to provide, and when the data are lacking, that assurance is lacking. Data collection must ensure that the strengths and weaknesses of the organization's practices and training programs are measured and compared with published results from other institutions. Verbal debriefing and written reports can give individuals and teams the performance feedback needed to work towards improvement. Trends in performance must be measured over time to detect areas that require more or less emphasis. Both short and long-term performance data must also be collected to serve as criteria for selection of new team members.

Risk management

It is not possible to eliminate risk from pediatric cardiac surgery. The best team operating with the best equipment in the best organization will not always achieve a successful outcome. Since risk cannot be eliminated, it must be managed through risk management, the cornerstone of which is the assessment and evaluation of risks.

The integration of quality assurance and risk management

Quality assurance programs can be linked with risk management programs. These latter programs attempt to manage and eliminate risk by establishing appropriate defences against errors at each of the three components that QA programs analyse.

The three quality assurance and risk management components interact in the following manner:

Structure: The structure of an organization comprises its personnel, equipment and environment, and administration. Risk management at this level involves applying preventive measures, such as constantly evaluating training and planning, personnel, equipment and environment, to minimize the chance of an error being made. Thus, risk prevention involves the prior evaluation of risk of an error being made. Personnel should be evaluated to ensure optimal numbers, proper credentials and staff well-being. Equipment should be evaluated to ensure that what is needed is present when required, is working, has been serviced regularly and is present in adequate numbers. There should be a plan for both phased and emergency replacement of equipment. The environment should be conducive to the activities that must be carried out. At the administrative level, policies and procedures should be considered and protocols developed to deal with critical events. At the regulatory level, an evaluation should be made as to whether or not the government and other regulatory authorities are supportive of appropriate health care.

Process: Process deals with what was done and how it was done. This is the stage of care where it is possible to detect, mitigate or recover from errors. Risk management strategies for the Process component focus on identifying high-risk activities and their potential for bad outcomes, and attempting to minimize complications by preventing the development of further problems. For example, it might be determined that even though a surgical team and equipment were functioning at their peak, the severity of a patient's condition might require that the patient be transferred to another, larger facility.

Outcome: In assessing the Outcome component, efforts are made to decrease the consequences of an error. QA programs in this area focus on what is measured and monitored. For example, a QA program would ask if near-misses are monitored and investigated or if only those with complications are assessed. The Outcome component of risk management focuses on trying to limit loss or damage after any complication and on formulating methods to prevent future problems. To this end, surgical programs need effective and timely methods to recognize, manage and investigate adverse outcomes, as well as adverse processes.

One of the most effective approaches to risk management is the development of a Critical Incident Review Policy.

Critical incident review policy

A critical incident review policy should provide immediate, multidisciplinary identification, management and review of critical incidents and accidents. To avoid impeding communication and facilitate fact-finding, the policy should be implemented non-judgmentally. Reviews might include any of the involved medical, nursing, or other staff. Consideration must also be given not only to the actions of the individuals involved, but to faults in the system in which those people work and which contributed to the problem.

At the HSC, a critical incident review policy for pediatric cardiac surgery might encompass those working in the cardiology clinic, radiology suite, pre-operative (pre-assessment) clinic and nursing unit, operating room, intensive care unit and post-operative nursing unit. In such a structure, it would be appropriate to appoint one or several team members to the position of risk manager.

A review would be triggered by the occurrence of either a 'critical incident' (one in which process of care was not as planned or anticipated, even though outcome of care was acceptable) or a complication or 'accident' (one with true adverse outcome, such as death or serious bodily harm). In addition, a review could be activated by a department head or senior administrator.

The goal would be to have an initial review conducted within 48 hours and a report completed within 72 hours. Before such a review was conducted, priority would be given to the care of the persons involved. All of the equipment should be isolated, the facts documented and the family informed. The hospital should have the facilities to care for and debrief family and staff members.

The review should consist of:

- a survey of the scene;
- a review of all documentation;
- the establishment of a timeline of events;
- a review of all other pertinent information; and
- a review of all pertinent policies and guidelines.

Within 48 hours, there should be a meeting of a review committee. The purpose of the meeting should be to corroborate facts, identify contributing factors and develop recommendations. Either the department head or risk manager of the major department involved should chair the meeting, which should include those involved in the event. Minutes should be kept but not necessarily circulated.

The department risk manager should prepare the report. The final form of the recommendations developed by the review committee should be submitted, with a plan for their implementation and monitoring to the hospital or health authority risk manager. This person may choose to release the recommendations to the patient's family, but the report need not become part of the patient's hospital record.

The responsibility for ensuring that recommendations are implemented should lie with the hospital and regional health authority or equivalent.

One of the issues that should be considered is that of the need for confidentiality of the proceedings of the review committee, and protection of the information obtained from public disclosure.

At present the medical standards committees of the hospital are protected from disclosure through provisions in provincial legislation that allow members of those committees to refrain from answering questions about the discussions at the committees. If there is to be openness in the discussion of matters at quality assurance and risk management reviews, consideration will have to be given to providing similar protection for those processes. However, the need for protection from disclosure of the discussions from those proceedings will need to be balanced against the right and the need for patients and their families to know what occurred. The detail of how that would be accomplished is beyond the scope of this report. However, it is safe to say that consideration needs to be given to providing for such protection and disclosure.

According to Davies's report, a review policy similar to that discussed above is currently in use by the Calgary Regional Health Authority (CRHA). This policy was developed from one originally proposed and implemented in the Department of Anaesthesia at Foothills Hospital.

There are probably others as well. They can serve as a model for what needs to be put into place at the HSC.

Team performance

Problems in leadership, teamwork, communication and decision-making loom large in this report's account of the history of the Pediatric Cardiac Surgery Program in 1994. The HSC needs to take steps to address these human factors, since problems with human factors play a significant role in contributing to negative surgical outcomes.

It is beyond the scope of this Inquest to provide a detailed description of the improvements in team performance that the HSC should undertake if the Pediatric Cardiac Surgery Program were to be restarted. However, it is clear that these efforts would need to be ongoing, as opposed to a simple start-up initiative.

Ongoing, overall initiatives to improve team performance

The initiatives would have to pay attention to:

- the necessity for team building through a briefing and orientation process that included all players;
- the initiation of pre-operative briefing sessions that focused on the plan for the operation (including the anaesthetic) and plans to address any contingencies, should problems arise with the patient, equipment or personnel;
- the planning and the use of standard operating procedures;
- the development of leadership skills;
- the provision for team development or maintenance;
- emphasizing team communication;
- clarity in the decision-making process;
- a process of conflict resolution;
- post-operative debriefing sessions (for all operations, regardless of outcomes); and
- a stress management component.

Team Training

An important element of team performance is training that is specifically designed to:

- decrease or reduce the probability of errors occurring;
- correct errors before they have an impact; and
- contain or decrease the severity of the consequences of those errors that have been made.

Such training focuses on the development of concepts and behavioural strategies as measures to manage error. Teams should learn to address those day-to-day issues, particularly those relating to communication and decision-making, that arise between different members of the team, such as between doctor and nurse or surgeon and anaesthetist. These issues require an understanding of how teams and their individual members manage errors.

One component of such a training program would involve training in the principles of crisis management, using simulations of critical incidents. The purpose of such crisis training is to:

- provide participants with predetermined responses to critical incidents which can be called upon when needed, and
- instruct participants in the co-ordinated integration of all available resources to maximize safe patient outcomes.

However, health-care workers need to learn how to work together, not only during crises but also, more importantly, under normal circumstances, when nothing goes wrong. Teams that normally work well together will probably make fewer errors and encounter fewer problems. Then, if things do go wrong, the team will have already dealt with any interpersonal and organizational difficulties before the crisis.

Training to manage error must be inaugurated into the earliest training of doctors, nurses and other health-care workers. Without this type of training from the start of professional life, health-care workers will find it difficult to support and enhance the change from doctor-based to true team-based care. To be effective, the value of quality assurance, risk management and team performance must become embedded in the HSC culture. This will require active promotion by senior staff responsible for training and evaluation. These senior staff will therefore need additional training themselves.

Both health-care workers and administrators should establish the details of the program. Effective programs in the operating room will involve surgeons, anaesthetists, operating-room nurses, anaesthetic assistants, perfusionists, anaesthetic (respiratory) therapists, technicians, unit assistants and clerical staff.

Such training cannot be a single lesson, taken once, and assumed to 'fix' the problem. Repetition and reinforcement are vital if the desired outcomes are to be achieved.

Finally, if there is to be a Pediatric Cardiac Surgery Program at the Winnipeg Health Sciences Centre, it must incorporate ongoing policies of quality assurance, risk management and team performance. These must be ongoing programs that stress the need to identify problems, develop and implement solutions and monitor to ensure that solutions work and do not introduce new problems.

RECOMMENDATIONS

It is recommended that: The Province of Manitoba consider legislation that requires hospitals throughout Manitoba to establish appropriate quality assurance and risk-management programs that accord with the principles and suggestions contained in this report, and that legislative protection be granted to the discussions that form part of those processes, provided that the right of patients and their families to full disclosure of what has occurred to them during the course of treatment is not compromised.

It is recommended that: The HSC, in conjunction with the Winnipeg Regional Health Authority, develop a quality assurance and risk management program employing the principles and suggestions contained in this report.

It is recommended that: The HSC exclude doctors who have been involved in a case that is under review by any of the hospital standards committees from participating in the decision-making process relating to such a review.

It is recommended that: The HSC Department of Surgery develop an appropriate database for all surgical procedures, but particularly for pediatric cardiac surgical operations. The database should include information such as cross-clamp times, cardiopulmonary bypass times, total circulatory arrest times, amount of blood products used and such other relevant information as would allow for the proper monitoring of surgical trends within a given program or for a particular surgeon.

It is recommended that: Pediatric cardiac surgical data be collected in a way that makes it possible to compare Winnipeg procedures with those performed in other centres.

It is recommended that: The HSC establish a clear policy on how staff is to report concerns regarding risks for patients. This policy must ensure that there is no personal or professional jeopardy to the person who is making the report. It should be clear to every staff member to whom they are to present such reports.

It is recommended that: The HSC administration ensure that all staff members are made aware of their responsibility to use incident reports and fully chart problems with the process of delivery of care and any complications in the outcome of care.

THE FUTURE OF PEDIATRIC CARDIAC SURGERY IN MANITOBA

- Finding

The evidence suggests that the Province of Manitoba lacks a sufficient population base to assure the establishment of a high-quality, full-service Pediatric Cardiac Surgery Program.

- **Finding**

The evidence suggests that there are real benefits to patients to having a high-quality, limited service pediatric cardiac surgery program in Manitoba that is integrated into a regional Pediatric Cardiac Surgery Program.

The available information suggests that the limited number of cases that can be undertaken in a province like Manitoba with a population of just over one million increases the risk of morbidity and mortality, particularly in the case of high-risk surgery. Even if the catchment area were expanded to include other areas such as Nunavut or Northwestern Ontario, the base population would still be quite small and the number of complex procedures would still not be large enough to support a full-service program.

However there are difficult issues associated with sending children to other provinces for pediatric cardiac surgery. Some children cannot tolerate travelling such distances very well. Some cannot travel at all. A program that relies exclusively on extra-provincial transportation could contribute to their greater risk and might even doom some of them to death.

There are also the emotional, psychological and physical tolls that are exacted on families who have to travel long distances under very stressful circumstances to face a difficult ordeal, without the strength and support of nearby family members. It seems both unnecessary and unfair to require parents and families of small children and infants to have to travel to other parts of the country in order to have relatively simple procedures performed. Additionally, the cost of delivering all pediatric cardiac surgery services to the citizens of Manitoba by sending them out of province is tremendously expensive.

Collins, who originated the idea of having a full-service program in this province, felt strongly that medical treatment is better when the diagnostic and medical treatment facility and the surgical facility are one and the same, and the surgical team knows the patient and family.

There is merit, as Collins testified, to having a facility where the surgical team can be involved in the initial diagnosis and treatment of a patient and will be involved in the post-surgical treatment and where parents, as well as the patients, are fully prepared for surgery. Where possible, treating a child in such a centre is psychologically preferable to transporting a child to a centre where the surgical team (figuratively speaking) meets the patient the day before surgery and sends the child 'back home' a few days later.

In addition, every province needs to have at least one facility where a full range of services can be provided to the patients who are brought into care. In concert with that, developments in related fields might require the existence of a pediatric cardiac facility. The developing field of invasive pediatric cardiology—which can reduce the number of pediatric cardiac surgical procedures—requires that a pediatric cardiac surgeon be available in the event of complications. If there is no pediatric cardiac surgeon, it would be difficult, if not impossible, to attract such leading-edge pediatric cardiologists to Winnipeg.

Dr. Brian Postl testified that regionalization of pediatric cardiac care in Western Canada has been under consideration since the closure of the Winnipeg program. Such a model might involve the establishment of a regional pediatric cardiac centre in a central location (such as Edmonton). Under this system, a local surgical team would perform lower-risk procedures in Winnipeg. Complex cases would be transferred to the regional centre. If necessary, a surgeon capable of performing complex procedures could travel to Winnipeg and other locations to perform scheduled procedures. Such a program must, of course, pay close attention to the issues of team-building, training, communication and decision-making that have been identified throughout this report. If a surgeon is flown into Winnipeg to perform an operation, the surgeon must also become a well-integrated member of the team. He or she must develop a degree of familiarity and comfort with local team members. Team performance on a regional basis would have to be considered.

RECOMMENDATIONS

It is recommended that: The HSC, the Winnipeg Regional Health Authority and the Manitoba Department of Health pursue discussions with provinces in Western Canada for the development of a Western or Prairie regional Pediatric Cardiac Surgery Program.

It is recommended that: A provincial Pediatric Cardiac Surgery Program be developed at the HSC that is limited to undertaking lower and medium-risk procedures, but can undertake more complex procedures in conjunction with a regional pediatric cardiac surgery centre.

It is recommended that: The Province of Manitoba develop a financial assistance package for families required to travel out of province for surgical treatment of family members. The package should ensure that family members are in no worse a financial position than if the treatment had been provided in Manitoba.

COMBINING THE ICUS

Legitimate questions were raised throughout 1994 about the decision to have both the neonatal intensive care unit and the pediatric intensive care unit provide service to the Pediatric Cardiac Surgery Program. The evidence suggests that pediatric cardiac surgery patients should be treated in one ICU.

It is recommended that: As a part of any planned restart of the Pediatric Cardiac Surgery Program, the post-operative care of pediatric cardiac patients be centralized in a single intensive care unit.

REFERRAL TO THE COLLEGE OF PHYSICIANS AND SURGEONS OF MANITOBA

- **Finding**

  The evidence suggests that there may be a need for the College of Physicians and Surgeons of Manitoba to investigate the evidence set forth in these proceedings to determine if other proceedings may be necessary.

A number of facts that were disclosed in the evidence suggest that appropriate medical standards may not have been met. It is not the role of this Inquest to determine whether there are grounds for disciplinary or any other action as a result of any such finding. Where medical professionals have not performed their responsibilities in an appropriate manner, or in a manner that meets an appropriate professional standard, the College of Physicians and Surgeons has a responsibility to conduct an investigation and determine if disciplinary proceedings should be undertaken.

According to the evidence of Dr. Ken Brown, the registrar of the College, no official complaint has ever been filed with the College with respect to any of the medical professionals associated with the care of the patients whose deaths were the subject of these proceedings. Therefore the College has never undertaken any official investigation of any of these cases from a disciplinary perspective. This apparently stems from a policy that the College maintains of waiting for a formal complaint before undertaking any such proceedings.

It is recommended that: The College of Physicians and Surgeons of Manitoba revamp its policies and procedures so that in the future investigations and disciplinary proceedings no longer depend on whether or not a formal complaint has been filed with the College.

It is recommended that: The College of Physicians and Surgeons review this report to determine if there are grounds for undertaking disciplinary proceedings against any of the medical professionals involved in the care of any of the 12 children whose deaths were the subject of these proceedings.

CONCLUSION

Life is a precious and fragile gift. The gift to the parents of the children who were the subject of these proceedings lay in what they could be. Born with the burden of a defective heart, they yet stood on the threshold of possibility. For reasons beyond their control, however, their possibilities were not to be realized.

The events surrounding their deaths have been examined in considerable detail and the findings and recommendations that seem appropriate have been set out. But for the families, that may never be the end of it.

The evidence suggests that some of the children need not have died. The Paediatric Death Review Committee of the College of Physicians and Surgeons, in its annual report for 1994, classified four of the twelve cases (without identifying which cases) as being possibly preventable with improved medical management. I believe that that number could be even higher.

The evidence from these proceedings suggests that the deaths of Jessica Ulimaumi, Vinay Goyal, Marietess Capili, Jessie Maguire and Erin Petkau involved some form of mismanagement, surgical error or misadventure and were all at least possibly preventable or preventable. The operations on Daniel Terziski and Erica Bichel involved procedures that were probably outside the ability of the surgeon and the team to attempt and ought not to have been done in this province. The operation on Shalynn Piller was outside the permitted parameters applicable to the team at the time of the operation and also ought not to have been done in this province.

The deaths of Gary Caribou, Alyssa Still and Ashton Feakes are still surrounded by more questions than answers. Only the death of Aric Baumann from a fatal and untreatable disease has been acceptably explained.

Much of the time involved in the writing of this Report has been spent in determining what occurred and when and how. To a certain extent there remains the question of why. To that there are no easy answers. The best that this report and the hearings could do is to uncover the events of that year and reveal what went on. To the extent that there are reasons for what occurred, they are offered in this and preceding chapters.

Yet we are faced with the fact that the parents of these children have been left with a great burden: the loss of a child. Parents are not supposed to outlive their children. Those parents have no choice but to try to adapt to that situation.

For some of them, this proceeding may have provided a catharsis, but for others it has not. Some of the families feel the obligation to take the matter of their children's deaths further, through other types of proceedings and actions. For some of the families, a belief in a Higher Power has allowed them to come to terms with what has happened. For others, there is nothing, I suspect, that will bring them peace. If they can find any solace in this report, it is in the knowledge that the details of the tragic events of 1994 have finally been brought to light.

However, there is something that must be stated clearly.

From all of the facts and evidence that have been uncovered, there is one that stands out. The deaths of these children were not the result of any failing on the part of the parents. There was nothing that these parents did that they ought not to have done. There was nothing that they did not do that they should have done. Faced with the situation that each of them saw, they did what they believed was best for their child and they acted on the basis of the best information that they were able to obtain.

Yet of all those who have been involved in this sad proceeding, the parents will continue to carry the greatest burden.

For that, we owe them the commitment to do all that we can to ensure that this does not happen again.

Appendix 1

GLOSSARY OF TERMS USED IN THIS REPORT

Acidemia A condition in which the blood is more acid and less alkaline than normal.

Acidosis An abnormal condition resulting from an increase in acids or from a depletion of alkali in the blood and body tissues.

Acute A term used to describe a condition that appears suddenly or one that has a short and relatively severe course.

Adrenalin A drug that is used to increase the blood pressure, heart rate and force of contraction of the heart. This results in an increase in cardiac output from the heart. Injection of adrenalin, which is also known as epinephrine, may cause an irregularity of the heartbeat or an arrhythmia.

Alkalinity An abnormal condition resulting from a decrease in acids or from an increase of alkali in the blood and body tissues.

Anaesthesia A field of medicine involving the administration of drugs that produce a loss of consciousness or sensation. The term also means a drug-induced state of lack of feeling. This may affect the entire body (as in general anaesthesia), a region of the body (as in regional anaesthesia), or a small amount of tissue (as in local anaesthesia).

Anaesthetist A doctor who is specially trained to administer anaesthesia.

Annulus A structure shaped like a ring. For example, in the heart, the base of the mitral valve is termed the annulus.

Aorta The large artery that takes blood from the left ventricle of the heart to the body.

Aortic Pertaining to the aorta.

Aortic arch The second part of the aorta, which continues on from the ascending aorta and curves to the left and posteriorly (or backwards).

Aortic valve The valve in the heart between the left ventricle and the aorta. It has three flaps or cusps.

Arrhythmia An abnormal rhythm of the heart.

Artery A blood vessel that carries blood from the heart to various parts of the body. Most arteries carry blood that is rich in oxygen or well oxygenated. The main exception is the pulmonary artery.

Arterial pressure The blood pressure in the arteries of the systemic circulation.

ASA physical class A classification system adopted by the American Society of Anesthesiologists (ASA) and used by anaesthetists to assess the pre-operative physical state or condition of a patient. There are five categories, and adding the postscript 'E' indicates that the patient is to undergo an emergency operation. The ASA Class does not correlate with the risk of the anaesthetic, but does roughly correlate with the risk of post-operative complications.

Ascending aorta The first part of the aorta, which arises from the left ventricle and gives off the right and left coronary arteries before continuing as the aortic arch.

ASD See **Atrial septal defect**

Atresia The absence or closure of a normal body opening or tubular structure. For example, in pulmonary atresia there is blockage of the passage between the right ventricle and the lungs.

Atrial Pertaining to the atria.

Atrial septal defect (ASD) An abnormal opening or hole in the septum between the right and left atria. Normally, the flow of blood will be from left to right (left to right shunt). Blood flow from right to left (right to left shunt) will be present only if there are other complicating conditions leading to a higher pressure on the right side, such as pulmonary stenosis or tricuspid atresia, which impede or prevent the normal flow of blood from the right ventricle to the lungs.

Atrioventricular (AV) canal defect A defect in the heart in which there is a large hole in the centre of the heart. There are abnormal openings in the atrial and/or ventricular septa at the level of the atrioventricular valves. There are also often abnormalities of the mitral and/or tricuspid valves. These defects are also known by the inclusive term 'persistent common atrioventricular canal deformities'. There are three variants, which may be classified as partial, intermediate and complete AV canal deformities.

Atrioventricular (AV) valves The two valves that lie between the atria and the ventricles. These valves are the tricuspid (right) and the mitral (left) valves.

Atrium Either of the two upper chambers of the heart, in which blood collects before being pumped to the ventricles. (The plural is atria.)

AV See **atrioventricular valves**

Azygous vein An unpaired vein in the chest, which serves to connect the superior and inferior vena cavas, as well as the right intercostal veins.

Bicuspid aortic valve An abnormality of the aortic valve in which there are only two cusps, instead of the normal three.

Blalock-Taussig shunt An operation performed in cases of congenital pulmonary stenosis. An anastomosis is created between the aorta (or one of its branches, such as the subclavian artery) and one of the pulmonary arteries. This allows some of the blood from the systemic circulation to be shunted into the pulmonary circulation.

Blood pressure (BP) The force or pressure exerted by the heart in pumping blood through the arteries.

BP See **Blood pressure**

Cannula A tube inserted into a vessel to act as a channel for the transport of fluid. Cannulas come in different styles and sizes.

Cannulation The act of insertion of cannulas into blood vessels. This is a normal part of cardiopulmonary bypass.

Cardiac Pertaining to the heart.

Cardiac arrest When the heart stops on its own or is stopped from beating through drug or mechanical means.

Cardiac catheterization Examination of the heart by the passage of a thin tube or catheter into an artery or vein and up to the heart. This is done to sample oxygen, measure pressures and make X-ray videos of how the heart functions.

Cardiac output The volume of blood pumped by the heart each minute. The amount of cardiac output equals the volume of blood ejected with each heart beat (or stroke volume) multiplied by the heart rate.

Cardiac surgery Surgery on, within and around the heart. This may be open or closed-heart surgery.

Cardiology The study of the heart and its functions in health and disease.

Cardioplegia Intentional cardiac arrest or stopping of the heart (to allow cardiac surgery) by injection into (or perfusion of) the coronary arteries with a special salt or blood solution. The solution may be cold or warm and may contain different chemicals and drugs. Repeated injections are necessary for prolonged operations.

Cardiopulmonary Pertaining to the heart and lungs.

Cardiopulmonary bypass (CPB) Diversion of the venous blood going to the heart into a machine via a cannula. The machine then adds oxygen and removes (if necessary) carbon dioxide from the blood and pumps it via another cannula into the arterial side of the circulation, bypassing the heart.

Cardiovascular Pertaining to the heart and blood vessels.

Cardioversion Correction of an abnormal heart rhythm and restoration of normal rhythm by delivery of one or more mild electric shocks through the chest or directly onto the heart. The machine used is called a cardioverter (or defibrillator).

Catheterization The act of insertion of a catheter into a vessel or tube, which could be an artery, a vein or a bladder.

Central venous pressure The pressure in the right atrium and large veins of the chest. An estimate of this measurement may be made by examining the large (jugular) vein in a patient's neck. The pressure may also be measured directly by inserting a special cannula into the jugular vein. This measurement can give an estimate of the adequacy of the return of venous blood to the heart and how the right side of the heart is functioning.

CHF See Congestive heart failure

Circulating nurse An operating-room nurse who does not 'scrub in' and does not wear sterile clothing (except to relieve the scrub nurse). The circulating nurse helps prepare the patient for the operation, may assist the anaesthetist and carries out non-sterile surgical tasks, such as opening packets of sutures, or obtaining equipment from outside the operating room.

Closed-heart surgery Surgery carried out on and around the heart, and without use of a heart-lung machine or stopping the flow of blood to the heart.

Coarctation of the aorta A constriction or narrowing of the main blood vessel (aorta) that carries blood from the heart to the body. The narrowing is situated somewhere along the vessel and restricts blood flow from the heart to the rest of the body. Patients with coarctation generally have hypertension with high blood pressures in the arms and low pressures in the legs. They may also have associated hypertrophy of the left ventricle and a heart murmur, and may present with cardiac failure.

Complete atrioventricular canal defect The most severe type of the atrioventricular canal deformities. This lesion is characterized by direct communication between the right and left ventricles and absence of the openings to the mitral and tricuspid valves.

Complete heart block Complete blockage of the heart's normal electrical current between the atria and ventricles. This condition almost always requires treatment with a pacemaker, after emergency treatment with drugs (and sometimes with external cardiac massage).

Congenital Refers to conditions that are present at birth, regardless of their causation.

Congestive heart failure (CHF) The inability of either the right or the left ventricle to pump all the blood that returns to it. As a result, blood backs up in the blood vessels leading to that ventricle and the vessels become congested with blood. Failure of the right ventricle (or right heart failure) leads to blood backing up in the liver and legs. Failure of the left ventricle (or left heart failure) leads to blood backing up in the lungs.

Coronary arteries The two arteries, right and left, which arise from the ascending aorta, curve down over the top of the heart and then branch out over the surface of the heart. The right coronary artery (RCA) supplies most of the right ventricle, while the left coronary artery (LCA) supplies most of the left ventricle. These arteries supply the working heart muscle with oxygen. Blockage of an artery or one (or more) of its branches may lead to the heart being starved of oxygen, causing a myocardial infarction.

CPB See Cardiopulmonary bypass

Cross clamp (X-clamp) A special clamp that is applied to the aorta to prevent the flow of blood through the aorta while some type of surgical procedure is performed on the heart or the aorta.

Cross-clamp time The length of time that the aorta is cross-clamped and blood does not flow through the aorta (or into the coronary arteries).

Cusp The flap or leaflet portion of any of the heart valves that forms the movable part of the valve.

Cyanosis A bluish discolouration of the skin that indicates that the hemoglobin in the blood has a reduced amount of oxygen. Peripheral cyanosis (for example, of the fingernails) occurs when there is a reduction in blood flow to the extremities. Central cyanosis (for example, of the tongue) occurs when there is lung or heart disease, such as a right to left shunt or inadequate breathing.

Definitive repair Surgical repair of a lesion, which corrects the underlying abnormality.

Deoxygenated Having a reduced amount of oxygen, as in deoxygenated or 'blue' blood.

Descending aorta The part of the aorta that curves down from the heart and extends down into the abdomen to where the aorta branches into the common iliac arteries.

Diastolic Pertaining to diastole or the relaxation phase of the heart's pumping cycle.

Digoxin A drug often used in the treatment of congestive heart failure. Digoxin makes the heart muscle pump more strongly, slows the rate or speed at which the heart beats and increases blood flow to the kidneys, which helps in the removal of excess fluid from the body. The same drug is sometimes used to treat certain arrhythmias.

Distal Away from. (The opposite of proximal.)

Diuretic A drug that increases the production of urine by the kidneys. As a result, a patient may excrete more water and salts from the body.

Double outlet (right) ventricle A condition in which both the pulmonary artery and the aorta connect to the right ventricle.

Ductus arteriosus An arterial duct or vessel in the fetal heart that connects the left pulmonary artery to the descending aorta. The ductus arteriosus allows blood to bypass the lungs in the fetal circulation and normally closes shortly after birth. If it does not close, the condition is termed patent ductus arteriosus.

Dysplastic Any tissues that are abnormally developed.

ECG See Electrocardiogram

ECHO See Echocardiogram

Echocardiogram (ECHO) The use of ultrasound to produce images of the inside of the heart and how it works.

ECMO See Extra-Corporeal Membrane Oxygenation

EKG See Electrocardiogram

Electrocardiogram (ECG or EKG) A graphic record of the electrical impulses produced by the heart. This record shows the rate, rhythm and site of origin of these electrical impulses, as well as if the patient has had damage to the heart, such as a heart attack.

Extra-Corporeal Membrane Oxygenation (ECMO) A method of providing life-support for a patient whose heart and/or lungs have failed. ECMO is a form of long-term cardiopulmonary bypass. A cannula takes blood from the body to a special membrane outside the body (or extracorporeal), where oxygen is added and carbon dioxide is removed. The blood is then returned to the body through another cannula.

Epinephrine A drug that is used to increase the blood pressure, heart rate and force of contraction of the heart. This results in an increase in cardiac output from the heart. Epinephrine, which is also known as adrenalin, may cause an irregularity of the heartbeat or an arrhythmia.

Fetal Pertaining to the fetus.

Fetus A human embryo before birth.

Foramen ovale A natural opening in the septum between the two atria that allows blood to bypass the lungs in the fetal circulation. Failure of the foramen ovale to close leads to a defect in the septum known as a patent foramen ovale or PFO.

Heart block The interruption or blockage of the normal conduction of electrical impulses in the heart. Heart block is classified as first degree, second degree or third degree (also known as complete heart block).

Heart failure Inability of the heart to pump sufficient blood (or cardiac output) to the body and/or the lungs. Heart failure can affect either the right ventricle or the left ventricle or both. As a result, blood backs up in the blood vessels leading to that ventricle and the vessels become congested with blood. Failure of the right ventricle (or right heart failure) leads to blood backing up in the liver and legs. Failure of the left ventricle (or left heart failure) leads to blood backing up in the lungs. This may then lead to right heart failure. Sometimes the term congestive heart failure (CHF) is used to describe left heart failure.

Heart murmur An abnormal sound heard when the heart beats. This sound may result simply from increased blood flow in the heart—the murmur is termed physiological and is not considered serious. Other murmurs are caused by blood flowing through abnormal openings in the heart (such as a patent foramen ovale) or through an abnormal heart valve (such as aortic stenosis).

Heart sounds Noises produced as the heart valves open and close in precise sequence, allowing blood to flow forward into the next chamber and not backward. It is the closing of these valves that produces the heart sounds, as in the familiar 'lub-dub.'

Hemoglobin The special compound in red blood cells to which oxygen attaches.

Hemorrhage Bleeding or loss of blood, which may be sudden (acute) or chronic.

Heparin A drug used to decrease the ability of the blood to clot, resulting in an increase in (or prolongation of) the clotting time. In cardiopulmonary bypass, heparin is used to prevent clots from forming in the heart-lung machine.

Hypertension An increase in blood pressure, either of the systemic circulation or of the pulmonary circulation.

Hypertrophy An increase in size or overgrowth of a tissue or organ. In the heart, either the left or the right ventricle may hypertrophy in response to increased work of pumping blood.

Hypoplasia Underdevelopment of a tissue or organ. An example would be hypoplasia of the aortic arch, where blood flow to the body is hampered by an underdeveloped and therefore restricted aortic arch.

Hypoplastic Pertaining to hypoplasia or underdevelopment.

Hypoplastic aortic arch Underdevelopment of the aortic arch, leading to restricted blood flow through the aorta.

Hypoplastic left-heart syndrome A complex group of congenital heart lesions, including hypoplasia or even complete absence of the left ventricle and severe hypoplasia of the aorta. There may also be a combination of aortic and mitral valve stenosis or aortic and mitral valve atresia.

Hypoplastic left ventricle Underdevelopment of the left ventricle of the heart.

Hypothermia A reduction in the central or core temperature of the body below 36 degrees Celsius. In cardiac surgery, a patient may be made hypothermic, by infusing cold liquids into the circulation and/or packing ice around parts of the body. This is done in order that the flow of blood to the brain and other tissues may be reduced, thus allowing the surgeon to safely repair the heart, without damage occurring in the organs that would otherwise be starved of oxygen. With deep hypothermia, the patient (usually an infant) is intentionally cooled to about 16 to 20 degrees Celsius. This allows surgeons to be able to stop the heart for about 45–60 minutes and to operate without either the heart moving or tubing or blood being in the very small operative field.

Hypoxia A reduction in the amount of oxygen available for use by the tissues of the body.

Hypoxic Pertaining to a reduction in the amount of oxygen.

Inferior vena cava (IVC) The major vein that carries the deoxygenated blood from the lower limbs and most of the organs of the pelvis and abdomen. The IVC returns this blood to the right atrium.

Interrupted aortic arch When the aorta does not develop completely in the area of the arch. As a result, the aorta is divided into two parts that are not connected to each other, preventing blood flow through the aorta.

Intracardiac Within the heart.

Invasive A technique of studying the body in which instruments are inserted inside the body.

IVC See **Inferior vena cava**

JET See **Junctional ectopic tachycardia**

Junctional ectopic tachycardia (JET) A very rapid heart beat that can be fatal if not properly controlled.

Left-to-right shunt Abnormal direct passage of oxygen-rich blood from the left side of the heart to the right side, at the level of the atria or the ventricles.

Left ventricular failure When the left ventricle is unable to pump all the blood out through the aorta. The blood then backs up within the left ventricle and then progressively into the left atrium and into the lungs. Fluid then builds up in the lungs.

Ligate To tie off, by application of a ligature or suture. For example, in cardiac surgery, the surgeon may ligate a patent ductus arteriosus.

Ligature A thread or suture that is tied tightly around a blood vessel or another structure.

Mitral valve The heart valve between the left atrium and the left ventricle. This valve has two flaps or cusps and is one of the two atrioventricular valves.

Murmur An abnormal heart sound.

Neonate A newborn child aged from birth to six weeks.

Norwood operation or procedure A stage in the surgical treatment of hypoplastic left heart syndrome. In this operation, a pulmonary homograft is used to enlarge the rudimentary aortic arch and then join it to the functioning pulmonary artery.

Open-heart surgery Surgery carried out on the heart that is opened or its major blood vessels, while the blood is diverted through a heart-lung machine.

PA See **Pulmonary artery**

Pacemaker An electrical device that can be used to replace the heart's defective natural pacemaker or conduction pathway. The artificial pacemaker emits a series of electrical discharges from a battery and so controls the rate and rhythm of the heartbeat.

Palliative Reducing the severity or alleviating the symptoms of a condition without curing the underlying abnormal condition. Does not usually offer a good long-term outcome.

Partial anomalous pulmonary venous return Oxygenated blood returning from the lungs is carried by one or more pulmonary veins emptying directly or indirectly through venous channels into the right atrium instead of the left atrium. This lesion functions in a manner similar to an atrial septal defect.

Patent ductus arteriosus (PDA) A condition in which the ductus arteriosus fails to close shortly after birth. This results in a significant right to left shunt of blood. Babies with this condition often develop heart and lung failure. Treatment with drugs (indomethacin) is possible, and surgical ligation is often necessary.

Patent foramen ovale (PFO) A failure of the foramen ovale to close, resulting in an opening in the septum between the two atria.

Pediatrics (Paediatrics) The branch of medicine that deals with the development and care of children, as well as the diseases and treatment of children.

PDA See **Patent ductus arteriosus**

Perfusion The act of forcing liquid to flow through the vessels of an organ. In heart surgery, the term perfusion refers specifically to use of the heart-lung machine for cardiopulmonary bypass.

Perfusionist A person who is specially trained to operate a heart-lung machine for cardiopulmonary bypass. In Canada, perfusionists are technicians, although in some countries, doctors act as perfusionists.

PFO See **Patent foramen ovale**

Pulmonary artery (PA) The large artery that carries blood from the right ventricle to the lungs.

Pulmonary artery stenosis Narrowing of the vessels involved in pulmonary blood flow caused by an underdevelopment of the area around the lung valve and along the pulmonary arteries. This narrowing can be anywhere from just a blockage at the valve to thickening below the valve. There can also be narrowing of the pulmonary artery above the valve, and the vessel can narrow into both of the branches that go to the lungs.

Pulmonary atresia Absence of the normal opening from the right ventricle into the pulmonary artery.

Pulmonary blood flow The flow of blood from the right ventricle through the pulmonary arteries to the lungs and back through the pulmonary veins to the left atrium.

Pulmonary circulation The circulation from the right side of the heart through the lungs to the left side of the heart.

Pulmonary hypertension An increase in pressure in the blood vessels of the pulmonary circulation.

The pulmonary trunk The common stem of the pulmonary arteries, which arises from the upper surface of the right ventricle and then divides into the right and left pulmonary arteries.

Pulmonary valve The valve in the heart between the right ventricle and the pulmonary artery.

Pulmonary valve stenosis An abnormal narrowing of the pulmonary valve. If the narrowing is mild and there are no other abnormalities, the patient may be symptom-free. Moderate and severe stenosis will impair the flow of blood to the lungs, and right ventricular hypertrophy will develop in response to the increased work of pumping blood through a narrowed opening.

Pulmonary vein stenosis Narrowing of the pulmonary veins.

Pulse The wave of increased pressure produced in the blood vessels of the body each time the left ventricle contracts.

Regurgitation The abnormal backward flow of fluid. In the heart, regurgitation occurs when blood flows backward through a valve and into a chamber from which it was already pumped. This increases the work of the heart.

Right-to left-shunt The abnormal direct passage of oxygen-poor blood from the right side of the heart to the left side, at the level of the atria or the ventricles. This blood does not pass through the lungs, with the result that there is a dilution or lessening of the amount of oxygen in the blood going to the body.

Scrub nurse An operating room nurse who 'scrubs in' and wears sterile clothing and gloves. This nurse helps the surgeon before the operation by preparing the instruments and other equipment that will be used and then during the operation by handing the instruments to the surgeon.

Septum A muscular wall that divides the two chambers on the right side of the heart from the two chambers on the left. The atrial portion of the septum divides the top chambers, the right and left atria. The ventricular portion of the septum divides the bottom chambers, the right and left ventricles. (Plural: septa)

Shunt A passage between two blood vessels or two chambers of the heart. A shunt may occur naturally (as in a left-to-right shunt though an ASD) or may be artificially formed (as in creation of a Blalock-Taussig shunt).

Stenosis Narrowing or constriction of an opening, such as a heart valve.

Sternotomy Incision into or through the sternum or breast bone.

Sternum The breast bone.

Stroke volume The volume of blood ejected by the heart with each heart beat.

Subpulmonary stenosis Narrowing of the entrance to the pulmonary valve in the right ventricle.

Superior vena cava (SVC) The major vein that receives the deoxygenated blood from the upper limbs and the head and neck. The SVC returns this blood to the right atrium.

SVC See **Superior vena cava**

Systemic blood flow Blood flow to the body, as opposed to pulmonary blood flow.

Tachycardia An abnormally rapid beat. In an adult, a heart rate of more than 100 beats per minute is termed a tachycardia. In a child, the definition of tachycardia depends on the age of the child and from which part of the heart the increase in heart rate originates.

TAPVC See **Total anomalous pulmonary venous connection**

TCA See **Total circulatory arrest**

TEE See **Transesophageal echocardiography**

Tetralogy of Fallot This congenital heart lesion has four major abnormalities. These are a hole or defect in the ventricular septum (VSD), displacement of the aorta overtop the ventricular septum, hypertrophy of the muscle of the right ventricle and obstruction to blood flow from the right ventricle or right ventricular outflow tract obstruction (which most often results from pulmonary stenosis). Babies with Tetralogy of Fallot are often referred to as 'Tet' babies.

Tet spells Patients with Tetralogy of Fallot can suffer from Tet spells or periods when they are extremely cyanotic. The symptoms are most often brought on by activity. Tet spells usually indicate an urgent need for repair of the heart defect.

Thoracotomy Incision into the chest wall.

Total circulatory arrest (TCA) Complete stoppage of the circulation of the heart, including complete stoppage of the heart-lung machine. This allows the surgeon to work on the heart without blood or perfusion cannula partially obscuring the surgical site. This technique requires deep hypothermia so that the tissues of the body, especially the brain, are protected from the prolonged lack of oxygen.

Total anomalous pulmonary venous connection (TAPVC) All of the oxygenated blood returning from the lungs is carried abnormally to the right heart by one or more pulmonary veins emptying directly or indirectly through venous channels into the right atrium instead of the left. A connection between the right and left atria (or inter-atrial connection) is necessary to allow oxygenated blood to reach the left side of the heart for distribution to the rest of the body.

Transesophageal echocardiography (TEE) A type of specialized examination of the heart, which involves performing echocardiography by placing the ultrasound probe in the patient's esophagus, rather than against the chest wall. When used during cardiac surgery, TEE allows the surgeon to evaluate the adequacy of the repair of the congenital heart defects, the adequacy of function of the ventricles and the valves and the presence of any residual intracardiac shunts.

Transposition of the great arteries/vessels A congenital abnormality where the two major blood vessels are switched in their positions, so that the aorta arises from the right ventricle and the pulmonary artery arises from the left ventricle. As a result, the pulmonary and systemic circulations work independently, producing a severe lack of oxygen after birth. Survival of the infant is possible only if there is a connection between the two circulations, such as an ASD, a VSD or a patent ductus arteriosus.

Tricuspid atresia Congenital absence of the normal valvular opening between the right atrium and the right ventricle. There is also a small right ventricle, a large left ventricle and decreased pulmonary circulation. Blood from the right atrium passes through an atrial septal defect into the left atrium, where it mixes with oxygenated blood returning from the lungs, then flows into the left ventricle and out into the systemic circulation. Blood reaches the lungs through an atrial septal defect and a ventricular septal defect.

Tricuspid valve The valve of the heart between the right atrium and the right ventricle. This valve is one of two atrioventricular valves.

Ultrasound High-frequency sound vibrations that cannot be heard by a human ear and are used in medical diagnosis. In pediatric cardiology, one use of ultrasound includes echocardiography, which gives a picture of the heart and how it functions. In obstetrics, ultrasound is used to monitor the development and well-being of the fetus.

Valve A membranous fold in part of the body that prevents the back-flow of blood or other fluids. In the heart, there are four valves that help propel the blood flow forward.

Vascular Pertaining to the blood vessels.

Vein A blood vessel that carries blood from various parts of the body back toward the heart. Most veins carry blood that is low in oxygen or deoxygenated. The main exception is the pulmonary vein.

Vena cava The major vein of the body, which carries blood back to the right side of the heart. The superior vena cava (SVC) drains the top part of the body, while the inferior vena cava (IVC) drains blood from the lower part of the body.

Venous Pertaining to veins.

Venous return The blood that is carried in the veins from all parts of the body (including the heart itself) back to the right side of the heart.

Ventricle One of the two lower pumping chambers of the heart.

Ventricular septal defect (VSD) An abnormal opening or hole in the septum between the two lower chambers or ventricles of the heart. Flow of blood is normally from left to right (left to right shunt), because of the higher pumping pressures produced by the left ventricle. If pulmonary hypertension develops, the shunt may be reversed, with blood flowing from right to left. This will result in oxygen-poor blood being delivered to the systemic side of the circulation, and the patient will appear cyanosed.

VSD See **Ventricular septal defect**

X-clamp See **Cross clamp**

Appendix 2

PARTIES TO THE PROCEEDINGS AND COUNSEL

The Crown was represented by Christina Kopynsky, Q.C., and Donald Slough.

The Manitoba Department of Health was represented by Issy Frost, Robin Winters, Tanys Bjornson and Jennifer Mann.

The Health Sciences Centre was represented by Richard Handlon and Rob Peters.

Laurie Maguire, mother of Jesse Maguire was represented by Martin Corne, Q.C. and Grenville Waugh.

The parents of Erin Petkau were represented by Brent Steward.

The parents of Marietess Tena Capili, Aric Baumann, Ashton Feakes, Alyssa Still and Daniel Terziski were represented by Saul Simmond, Darrell A. Kreel and Pat Fitzmaurice.

The surgeons and the cardiologists were represented by Ray Flett, Q.C., Tyler Kochanski, and Todd Campbell.

The neonatologists and the pathologists were represented by Richard Literovich and Catherine Howden.

The Department of Anaesthesia, HSC, and attending anaesthetists, and pediatric intensivists were represented by Hymie Weinstein, Q.C., and Mary Kate Harvie.

The Manitoba Association of Registered Nurses was represented by Colleen Suche, Q.C., William Gange and Holly Penner.

Appendix 3

LIST OF WITNESSES AND DATES OF TESTIMONY

	Last Name	Witness Name	Number of Days	Dates of Testimony
1	Armitage	Debra Joan	2	October 27, 28, 1997
2	Baumann	Deanna Marie	1	April 29, 1996
3	Bichel	Judith Murray Elaine	1	March 21, 1996
4	Bishop	Agnes J.	2	April 8, 9, 1998
5	Blanchard	Robert	5	February 17, 18, 19, 1998 March 2, 3, 1998
6	Borton	Joan	4	March 18, 19, 20, 1997 April 8, 1997
7	Boyle	Isobel	2	December 10, 11, 1997
8	Brown	Kenneth	2	July 28, 29, 1997
9	Burgess	Michael	1	August 26, 1998
10	Capili	Benedict Santos	2	June 6, 1996 September 29, 1998
11	Caribou	Charlotte Mary	1	March 20, 1996
12	Carnevale	Franco Angelo	1	September 23, 1998
13	Casiro	Oscar G.	1	March 12, 1998
14	Collins	George	3	December 16, 17, 18, 1997
15	Cornel	Garry	4	August 10, 11, 12, 13, 1998
16	Craig	Douglas Booth	3	January 15, 19, 20, 1998
17	Davies	Jan Margaret	3	September 14, 15, 16, 1998
18	DeNanassy	Joseph	1	May 28, 1998
19	Dixon	Karin Albina	2	December 16, 17, 1996
20	Doyle	Ellsabete	1	February 2, 1998
21	Drain	Sean	2	March 4, 5, 1996

	Last Name	Witness Name	Number of Days	Dates of Testimony
22	Duncan	Kim Fraser	4	August 11, 12, 1997 November 12, 13, 1997
23	Duncan	Walter James	2	May 12, 13, 1998
24	Embree	Joanne Elizabeth	1	June 3, 1998
25	Feakes	John Robert	1	May 1, 1996
26	Feakes	Linde Liesse	1	April 30, 1996
27	Feser	Donna Jean	3	October 29, 30, 1997 November 3, 1997
28	Fleming	Fiona	2	February 9, 10, 1998
29	Giddins	Niels Geoffry	17	May 8, 9, 13, 14, 15, 16, 29 30,1996 June 3, 4, 5, 1996 July 22, 23, 24, 26, 29, 30, 1996
30	Goyal	Sheena	1	March 11, 1996
31	Goyal	Vipan	1	March 11, 1996
32	Grimm	Paul Charles	1	March 9, 1998
33	Hamilton	Andrew	1	December 8, 1997
34	Hancock	Betty Jean	11	May 20, 21, 22, 1997 June 2, 3, 4, 5, 23, 24, 25, 25, 1997
35	Hawkins	Lois Elizabeth	4	March 12, 13, 14, 18, 1996
36	Hinam	Irene	7	November 26, 27, 28, 1996 December 9, 10, 11, 12, 1996
37	Hudson	Robert John	4	April 20, 21, 22, 23, 1998
38	Kesselman	Murray Samuel	4	January 8, 12, 13, 14, 1998
39	Kiesman	Colleen Louise	1	December 3, 1997
40	Koga	Todd Tadashi	2	August 20, 21, 1996
41	Maas	Michael Cornelius	5	July 31, 1996 August 1, 2, 1996 September 3, 4, 1996
42	Maguire	Laurie	1	May 27, 1996
43	Markesteyn	Peter Hermanus	3	March 23, 24, 1998 June 4, 1998
44	Martens	Catheryn Joy	1	March 16, 1998
45	Maxwell	Kelly-Anne	1	November 4, 1997
46	Mayer	John	1	August 25, 1998
47	McCudden	Christopher Joseph	2	September 24, 25, 1996
48	McGilton	Carol	4	November 19, 20, 21, 25, 1996
49	McNeill	Ann Marie	14	January 13, 14, 15, 16, 20, 21, 22, 23, 24, 27, 28, 29, 30, 31, 1997
50	Moffat	Michael	2	August 17, 19, 1998

	Last Name	Witness Name	Number of Days	Dates of Testimony
51	Odim	Jonah	25	September 4, 5, 8, 9, 10, 11, 12, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 29, 30, 1997 October 1, 6, 7, 8, 9, 10, 1997
52	Petkau	Barbara Elizabeth	1	April 16, 1996
53	Phillips	Susan	2	May 26, 27, 1998
54	Piller	Sharon Rhea	1	April 17, 1996
55	Postl	Brian	5	February 4, 5, 6, 1998 August 21, 1998 September 24, 1998
56	Reed	Martin Howard	1	March 5, 1998
57	Reimer	Heinz	6	April 9, 10, 28, 29, 30, 1997 May 1, 1997
58	Roberts	Susan	1	March 19, 1998
59	Rodger	James Lovell	3	March 5, 6, 7, 1996
60	Seshia	Mary Morton Katharine	2	January 6, 7, 1998
61	Shallcross	Susan	1	September 29, 1998
62	Shumila	Richard Beech	1	May 27, 1996
63	Smith	David Michael	2	October 30, 31, 1996
64	Soder	Christian	4	July 6, 7, 8, 9, 1998
65	Still	Donna Christine	2	April 15, 1996 September 28, 1998
66	Still	Shirley Mae	3	April 15, 16, 1996 September 28, 1998
67	Sutherland	John Beattie (Ian)	1	March 17, 1998
68	Swartz	Jo Stephanie	15	February 3, 4, 5, 6, 7, 13, 17, 24, 25, 26, 1997 March 10, 11, 12, 13, 17, 1997
69	Taylor	Glenn	3	June 22, 23, 24, 1998
70	Tena	Sarah	1	June 24, 1996
71	Tena	Teresida	1	June 26, 1996
72	Tenenbein	Milton	2	August 6, 7, 1997
73	Terziski	Danica	2	March 19, 1996 September 29, 1998
74	Thorfinnson	Arthur Rodney	2	September 2, 3, 1998
75	Ullyot	Suzanne Castling	6	November 24, 25, 26, 27, 1997 December 1, 2, 1997
76	Unruh	Helmut	4	January 21, 22, 1998 March 11, 1998 May 25, 1998
77	VanDeVelde–Coke	Susan	1	May 7, 1998
78	Wade	John	2	June 29, 30, 1998

	Last Name	Witness Name	Number of Days	Dates of Testimony
79	Ward	Cameron John Devon	1	December 6, 1995
80	Wasney	Mary Jane Rose	1	May 13, 1997
81	Weber	Celine	2	July 9, 10, 1997
82	Wiseman	Nathan	8	April 14, 15, 1998 May 4, 5, 6, 19, 20, 1998 June 1, 1998
83	Wong	Harley	4	May 5, 6, 7, 12, 1997
84	Wright	Helen	1	August 18, 1998
85	Youngson	Carol Jane	12	September 26, 1996 October 1, 2, 3, 15, 16, 17, 28, 29, 1996 November 12, 13, 1996 December 12, 1996